A Randomised Controlled Trial of Physical Activity Promotion in Primary Care

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Abstract

Aim of study: To compare the effectiveness of two contrasting communication styles with a no-intervention control group on self reported physical activity at 12 months follow up.

Study Design: 1-year randomised controlled trial.

Setting: Two large primary care medical centres in middle England.

Subjects: 1, 658, 45-64 year old, insufficiently active men and women.

Interventions: Thirty minutes of brief negotiation or direct advice, face-to-face, followed by 6 telephone contacts over 6 months.

Main outcome measures: Self reported physical activity at 12 months. Secondary outcome measures were change in blood pressure and body mass index.

Results: Both intervention groups and the control group significantly increased their physical activity over baseline ($p<0.05$). Intention to treat analyses revealed no between group differences for the combined intervention groups vs control and for brief negotiation vs direct advice. In treatment received analysis, the mean proportion change in physical activity for the brief negotiation group was 24% (95% CI 7 to 44) greater than controls with no significant difference between direct advice and controls. There was no change over baseline for body mass index in any group. Both the brief negotiation and the direct advice group reduced systolic blood pressure at 12 months but there were no between group differences. The brief negotiation group produced a –2.3 mmHg (95% CI –3.8 to –0.8) greater reduction in diastolic blood pressure than direct advice.

Conclusion: For patients already attending primary care for conditions that might benefit from increased physical activity, it would be worthwhile delivering approximately 20 minutes of brief negotiation to increase their physical activity. It would also be better to avoid instructing them about the need to change. It would seem to be a waste of limited resources to specifically invite patients into primary care for no other reason than to try to intervene in their level of physical activity.

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Preface

Ten years ago I was fortunate to meet Dr Tim Anstiss who fuelled my enthusiasm for seeking a solution to the struggle I was having trying to increase the amount of exercise undertaken by health club members. Between us we had various discussions about psychological theories that might guide future interventions and sketched many study designs onto scraps of paper. Dr Anstiss introduced me to a number of psychological therapies which seemed to have constructs which could help explain why people had such difficulty trying to become more active. However, I couldn't see an easy way of incorporating these ideas into routine practice. While training in one of the psychological therapies, I stumbled across the work of William Miller and Steve Rollnick on motivational interviewing. After reading their work I believed that an intervention based on the principles of motivational interviewing could be effective in changing people's level of physical activity and could easily be incorporated into routine practice.

Another chance encounter led to my meeting Dr. Margaret Thorogood who kindly gave me the opportunity to pursue my ideas in an academic environment.

I am very grateful to Dr Margaret Thorogood, my supervisor, for her guidance and encouragement during the last 5 years. Her belief in me gave me the confidence required to take on a piece of work of this magnitude. I am also grateful to Ian White for his statistical advice and patience.

Dr Tim Anstiss has since become a good friend and I am grateful for his emotional support during difficult times.

My thanks go to all the men and women who kindly took part in the study, the primary care teams at Redwell and Albany House Medical Centres, Gerald Dove for his clerical support and Dr. Jill Meara who helped us get started.

I'm particularly grateful to Charlie Foster who diligently delivered interventions to all the study participants while remaining a good friend.

I am very fortunate to have been able to draw upon the enormous experience and expertise of Professor Jerry Morris. I appreciate his guidance and assistance in completing the study.

Most importantly, I am grateful to Jane Dallison for her love and support.

This thesis is dedicated to my mother and my late father, Tony Hillsdon, who I hope would have been proud of what I have achieved.

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Chapter 1 The health benefits of physical activity

1.1 INTRODUCTION

Observational evidence suggests that physical activity and physical fitness reduce the risk of developing coronary heart disease, at least in middle aged men. There is also evidence that women and older adults benefit from being physically active. The relationship between physical activity and coronary heart disease (CHD) was first reported by Professor Jerry Morris in 1953. In a population study of approximately 31,000 male London Transport workers aged 35 to 64, Morris et al examined the relationship between the work that men did and the incidence of coronary heart disease. Two years of data revealed that bus conductors had an age adjusted risk of first coronary episode of 0.7 compared to bus drivers (Morris et al, 1953). Initially it was thought that perhaps the difference in 'mental strain' between drivers and conductors accounted for the difference in CHD rates. However, CHD rates for London Underground railwaymen were similar to the bus drivers and it was proposed that what both sets of workers had most in common and different from bus conductors, was the degree of physical exertion that their job required.

The idea that physical activity at work might protect men from early CHD held such promise for the researchers that they considered this proposition in the results of a parallel investigation of 110,000 male Post Office Workers and Civil Servants. The different types of work people did were ranked according the amount of physical activity they required with postmen regarded as the most active group and telephonists and clerks regarded as sedentary. During two years of study, standardised rates of first clinical

episode of CHD were 1.8/1000 in postmen and 2.4 in sedentary workers (Morris et al, 1953).

In a further prospective study of 687 London busmen, just a few years after their study in 1949-50, Morris and colleagues again observed significant differences in the incidence of ischaemic heart disease between bus drivers and conductors. In just over 5 years of follow up the rate of ischaemic heart disease was 1.8 times higher in drivers compared to conductors (Morris et al, 1966).

These landmark studies generated new hypotheses about the causes of coronary heart disease and as a result of the work of Professor Morris and his colleagues many other researchers have been inspired to test the hypothesis further. This chapter will provide an overview of this research which has led to international recommendations regarding physical activity and health.

1.2 DEFINITIONS OF MODERATE AND VIGOROUS PHYSICAL ACTIVITY

Physical activity can be measured in terms of frequency, the number of days per week a given activity is performed; duration, the length of time in minutes or hours that the activity is performed per occasion; and intensity, how hard the physical activity is. The intensity of physical activity can be referred to in relative or absolute terms. Relative physical activity intensity refers to the amount of effort exerted in undertaking a given activity relative to a person's maximum capacity for that activity. For example, it is usual to prescribe individual exercise as a percentage of maximal cardiorespiratory fitness expressed as millilitres of oxygen per kilogramme bodyweight ($V0_{2max}$). Moderate intensity physical activity is commonly described as 40%-60% of $V0_{2max}$ and vigorous

physical activity >60%-85% of $V0_{2max}$ (American College of Sports Medicine [ACSM], 1995). Percentages of maximum heart rate are also used as heart rate during aerobic exercise is strongly correlated with oxygen uptake.

The intensity of physical activity can also be expressed in absolute terms. This involves assigning a specific intensity to different activities. The units used to express intensity are usually either kilocalories per minute or METs. METs are multiples of the resting rate of oxygen consumption during any physical activity, with 1 MET representing the oxygen cost of sitting at rest which is approximately 3.5 mlO_2/kg/min (ACSM, 1995). In the work of Morris et al (1990) moderate intensity physical activity was assigned to physical activities that were deemed to entail an energy output between 5.0 but < 7.5 kcals/min while vigorous intensity physical activity was assigned to activities expected to have an energy output equivalent to ≥ 7.5 kcals/min. This coding system has also been used in a national survey of physical activity (Allied Dunbar National Fitness Survey, 1991). Moderate intensity exercise has been defined as an energy expenditure equivalent to 3-6 METs and vigorous intensity > 6 METs (Pate et al 1995). The main limitation of this approach to expressing the intensity of physical activity, is that as people age their VO_{2max} declines meaning that any activity of a given MET value requires a higher relative intensity. Therefore, walking at a brisk pace (over 4mph) might be moderate intensity for a person in their twenties and yet be vigorous for a person in their sixties. In an attempt to standardise the coding of different physical activities, tables of MET values for over 400 different physical activities have been published (Ainsworth et al, 1993).

Studies that explore the relationship between physical activity and various physiological outcomes typically have used relative measures of intensity whereas observational studies

exploring physical activity and mortality have used absolute intensity or a measure of total energy expenditure estimated from a combination of frequency, duration and intensity. Total energy expenditure is generally expressed either as kcals/kg bodyweight/week or MET hours/week.

Methods of measuring physical activity will be discussed in Chapter 5.

1.3 THE RELATIONSHIP BETWEEN PHYSICAL ACTIVITY AND PHYSICAL FITNESS

Any recall methods used to estimate levels of physical activity risk misclassification, not only due to recall errors but also due to some of the difficulties described above. An alternative is to measure physical fitness. Physical fitness has been defined as "a set of attributes that people have or achieve that relates to the ability to perform physical activity."(U.S. Department of Health and Human Services, 1996). It has the advantage of being measured objectively rather than the relying on self-report. One would expect that a more objective measure would lead to less misclassification. The most commonly studied component of physical fitness is aerobic power which is usually reported as maximal oxygen uptake ($V0_{2max}$), defined as the maximal capacity for oxygen consumption by the body during maximal exertion. It is also referred to as cardiorespiratory or endurance fitness.

The main determinant of physical fitness is physical activity. Other determinants include age, gender, health status and genetics. Fitness declines with age and is usually lower for women than men. Those in poor health would expected to be less fit than those in good health. It has been estimated that less than 50% of the variance in physical fitness

($V0_{2max}$) can be explained by genetics and that there is about 2.6 to 2.9 times greater variance in $V0_{2max}$ between families than within families (Bouchard et al, 1998). Physical activity intervention studies have shown that physical fitness can be significantly increased following a programme of regular physical activity by 5-14% depending on the intensity of exercise undertaken (Dunn et al, 1997).

1.4 STUDIES OF PHYSICAL ACTIVITY

During the same period as Morris et al (1953) were developing hypotheses about work activity and CHD, a prospective study of 191,609 male US railroad employees aged 40-64 was also investigating the relationship between occupational physical activity and all-cause mortality. Mortality rates were reported for clerks (least active) switchmen and section men (most active). Age adjusted death rates were 11.83/1000 for clerks, 10.29/1000 for switchmen and 7.62/1000 for section men (Taylor et al, 1962). The differences between section men and clerks were statistically significant.

Although these early studies of occupational physical activity were showing something of a trend they were criticised for not adjusting fully for potential confounding factors such as cigarette smoking and diet.

The focus of studies in the early seventies shifted away from occupational physical activity to leisure time physical activity. Professor Morris realised that work in most developed countries was becoming more mechanised and less active and that the potential of physical activity to contribute to public health could only come from leisure time physical activity (personal communication). Professor Morris and his colleagues

investigated the relationship between physical activity and CHD in a prospective study of 16, 882 civil servants aged 40-64 years who engaged in sedentary or light work. Between 1968-1970 the office workers recorded their leisure time physical activity on a Monday for the previous Friday and Saturday. In 1972 there were 232 cases of first heart attack cases which were matched to 428 controls. Men engaged in vigorous leisure time physical activity (> 6 METs) had a 67% lower risk of first heart attack compared to those engaging in non-vigorous physical activity. No significant relationship was observed between total physical activity and the incidence of CHD (Morris et al, 1973). In a further prospective study of 9,376 male civil servants, aged 45-64 with 9 years of follow up, men who reported participation in vigorous physical activity (> 6 METs) at least 3 times per week had an age adjusted relative risk of CHD of 0.36 compared to sedentary men. As with the earlier study this reduction was not observed for men engaged only in non-vigorous activity (Morris et al, 1990).

The Harvard Alumni study, an on-going prospective cohort study of 16, 936 male undergraduates from Harvard University showed that all-cause mortality declined with increased physical activity during 12-16 years of follow up (Paffenbarger et al, 1986). All cause mortality was 54% lower among men expending the equivalent of 3,500 kilocalories per week (kcals/week) in leisure time physical activity (approximately 3 hours of sport per week) compared with men expending less than 500 kcals/week (approximately 1 hour of sport).

The Multiple Risk Factor Intervention Trial (MRFIT) studied the relation of leisure time physical activity to first major CHD event and overall mortality in 12, 138 middle aged men during seven years of follow up. Leisure time physical activity was recorded for the

previous year and divided into tertiles. Compared to men in the lowest tertile of physical activity, those in tertile 2 had a 37% lower risk of CHD death and a 29% lower risk of death from all causes. No additional reductions in risk were observed for men in the highest tertile (Leon et al, 1987).

The British Regional Heart Study, a prospective study of middle aged men assessed the relationship between physical activity and the risk of heart attack during 8 years of follow up. The study reported a strong inverse association between physical activity and risk of heart attack. Men who were at least 'moderately' active (cycling or very frequent recreational activities or sporting activity once a week) had a 50% lower risk of heart attack compared with inactive (not engaged in regular walking or recreational activity) men even after adjusting for potential confounding factors (Shaper & Wannamethee, 1991).

Although the studies reported so far are limited to men, some evidence exists of similar benefits from increased physical activity for women. A large prospective cohort study of 40, 417, North American women aged 55-69 years, reported a 41% lower risk of all-cause mortality in women who engaged in moderate physical activity (light sports, golf, gardening, long walks) greater than 4 times per week compared to women who rarely performed any such exercise during 7 years of follow up. Even moderate activity performed as little as once per week had a relative risk of 0.71 compared to the referent group of moderate activity performed rarely or never. Vigorous physical activity (jogging, swimming, strenuous sports) was also associated with lower all cause mortality with a relative risk of 0.62 if performed greater than 4 times per week (Kushi et al, 1997).

A prospective study of 1,405 Swedish women studied the effect of occupational and leisure time physical activity on all-cause mortality during 6 years of follow up. Leisure time and occupational physical activity were divided into 4 groups. Group 1 for occupational activity included housewives and those predominantly engaged in desk work. For leisure time physical activity Group 1 included women reporting no physical activity. Group 4 for both categories was based on heavy physical labour or physical training which included swimming and jogging. Compared to the least active group women in group 2 (some physical activity at least 4 times per week including shop work and walking) had relative risks for all cause mortality of 0.28 for occupational activity and 0.56 for leisure time physical activity (Lissner et al, 1996).

Numerous other studies have shown an association between a physically active lifestyle and a reduction in all cause and CHD mortality (U.S. Department of Health and Human Services, 1996). Two meta-analyses of cohort studies relating to physical activity in the prevention of coronary heart disease concluded that the relative risk of developing coronary heart disease in the least active compared to the most active is 1.9 (Powell et al, 1987; Berlin & Colditz, 1990). The relative risk of coronary heart disease associated with inactivity is similar to other risk factors such as smoking, hypertension and elevated serum cholesterol (Pooling Project Research Group, 1978).

1.5 STUDIES OF PHYSICAL FITNESS

In addition to being physically active, maintaining a certain level of physical fitness has also been shown to be associated with reduced all-cause and cardiovascular mortality. A prospective study of physical fitness and cardiovascular mortality in 3,043 male US railroad workers aged 22-79 with an average of 20 years follow up, found that exercise heart rate (an estimate of physical fitness) was significantly related to cardiovascular and all-cause mortality. The adjusted relative risk of CHD mortality was 1.20 and 1.23 for all-cause mortality in those with exercise heart rates of 135 beats/min compared to those with rates of 105 beats/min or less (Slattery & Jacobs, 1988). These findings could be criticised for using an estimate of physical fitness although studies with better measures of physical fitness have reported higher relative risks for low fitness. Blair et al (1989) in a prospective study of 10, 224 men and 3,120 women studied physical fitness and risk of all cause-mortality with an average follow up period of 8 years. Physical fitness was measured by a maximal treadmill test. The relative risk of all-cause mortality in the least fit quintile compared to the most fit quintile was 3.44 for men and 4.65 for women. After adjusting for potential confounding the relative risks were 1.53 for men and 1.98 for women. Age adjusted relative risks for cardiovascular disease mortality climbed to approximately 8.0 for both men and women. A prospective study of 1,960 middle aged Norwegian men, investigated whether poor physical fitness was an independent risk factor for death from cardiovascular causes. The relative risk of death from cardiovascular causes after 16 years of follow up in the fittest quartile compared to the least fit quartile was 0.41 after adjusting for potential confounding factors (Sandvik et al, 1993).

1.6 CHANGES IN PHYSICAL ACTIVITY OR PHYSICAL FITNESS

The relationship between physical activity or fitness and reduced mortality could be explained by some kind of selection bias. It is possible that sedentary or unfit individuals may already have some degree of disease which causes them to be in these groups and prevents them from becoming more active or fitter. Physical fitness has a genetic component and it is possible that a genetic make up that is favourable towards higher levels of physical fitness also lowers the risk of disease. These concerns have been partly addressed by studies that show that changes in physical activity and physical fitness predict changes in mortality.

Further analyses of the Harvard Alumni Study found that men who increased their physical activity by at least 1,250 kcals/week during the 11-15 years between baseline and first follow up had a 28% lower risk of death in the following 11 years. Also men who reduced their physical activity during this period showed a graded increase in risk, although the trend was not quite significant ($p<0.057$ [Paffenbarger, 1993]). Similar results were observed in a follow up to the British Regional Heart Study. Men who were sedentary at baseline and who took up at least light activity during the 12-14 years of follow up, had significantly lower all-cause mortality in the 4 years after first follow up compared with men who remained sedentary, even after adjusting for potential confounding factors (risk ratio =0.55 [Wannamethee, 1998]).

Increases in physical fitness also predict reductions in mortality. A prospective study of 9, 777 men, with 2 measures of physical fitness 4.9 years apart studied the risk of mortality in those who changed their fitness during 5.1 years of follow up after the second measure. Men who improved from unfit to fit reduced their risk of all-cause mortality by

44% compared to men who were unfit on both occasions (Blair et al, 1995). Another prospective study of 1,932 men aged 40-60 years measured fitness on two occasions an average of 10 years apart. There was a graded, inverse relationship between changes in physical fitness and mortality whatever the baseline level of physical fitness. A 1 standard deviation increase in fitness between baseline fitness and the second measure led to a 30% reduction in the risk of death during 13 years of follow up after adjusting for all other potential confounding factors (Erikssen, 1998).

1.7 OTHER HEALTH EFFECTS OF PHYSICAL ACTIVITY

Apart from the effect on all-cause and cardiovascular mortality greater physical activity and physical fitness impact on a range of other health outcomes. Physical activity and physical fitness are associated with a lower risk of premature hypertension (Paffenbarger 1991; Blair et al 1984), non-insulin dependent diabetes (Ivy et al, 1999) colon cancer (Macfarlane & Lowenfels, 1994), breast cancer (Thune et al, 1997) and osteoporosis (Wolff et al, 1999). Physical activity and physical fitness also positively impact on risk factors for cardiovascular disease including blood lipids (Stefanick & Wood, 1994) and glucose tolerance (Ivy et al, 1999).

In addition, physical activity prevents significant future weight gain and helps control weight in those already overweight (Haapanen et al, 1997; Grilo 1995), two important considerations with the increasing prevalence of overweight and obesity. Another important finding is that in men who are already overweight, maintaining a reasonable level of fitness may reduce the risk of all cause mortality compared to normal weight low fit men. A prospective study of physical fitness and all cause mortality in 25, 714 men

with an average age of 44 years and with approximately 10 years of follow up, examined the relationship between low fitness and mortality for normal weight, overweight and obese men. The study found that low fitness (the lowest quintile) was an independent predictor of mortality in all body mass index groups even after adjustment for potential confounders (Wei et al, 1999). The relative risk of all cause mortality in low fit men was 2.2 (1.8-2.8) for normal weight, 2.5 (2.1-3.0) for overweight and 3.1 (2.5-3.8) for obese men when compared to normal weight men not in the low fit group. In fit men there was no significant trend in risk across bodyweight categories. It appears that physical activity can prevent significant weigh gain in those who are not overweight, help reduce weight in those who are overweight and reduce the health risks associated with being overweight.

Early reviews of physical activity in the treatment of hypertension concluded that physical activity reduced blood pressure in mild to moderate hypertensives by an average of 6-7mmHg (Arroll & Beaglehole, 1992; Hagberg & Brown, 1995). However, a more recent review of community based trials of non-pharmacological treatments for lowering blood pressure did not find that physical activity significantly reduced blood pressure (Ebrahim & Davey Smith, 1998). This discrepancy may be explained by the difference in the type of studies included in the different reviews. The earlier reviews mainly included efficacy studies where the amount of exercise being undertaken was supervised and compliance was high, whereas the Ebrahim and Davey Smith review focused on community based effectiveness trials where the exercise was unsupervised and compliance would therefore be more of a problem. Independent of changes in blood pressure, physically active and fit hypertensive men have a reduced risk of mortality compared to sedentary and unfit hypertensive men (Paffenbarger et al, 1993; Blair et al, 1996).

Particularly in older adults, increased physical activity improves the health related quality of life including activities of daily living and psychological health (King et al, 1993). A recent review of physical activity on mental well-being highlighted the important role physical activity can play in the treatment of depression and anxiety as well as in the general promotion of mental well being (Fox, 1999). Given the high prevalence of depression in England and the fact that the majority of it is managed in primary care (Meltzer et al, 1995), physical activity should be considered as part of the overall treatment of depression by general practitioners.

1.8 RECOMMENDATIONS FOR PHYSICAL ACTIVITY

The wealth of evidence relating to physical activity and health that has emerged in the last 40 plus years has led to a number of national and international recommendations about how much exercise people should take to benefit their health (Table 1.1).

Table 1.1 Recommendations for physical activity and health

Source	Recommendation	Reference
Commonwealth Department of Human Services and Health, Australia	Increase participation in physical activity. Based on the percentage of adults who, in the past 2 weeks, did not engage in any vigorous exercise, moderate exercise, or walking for recreation or exercise	Commonwealth Department of Human Services and Health, 1994
Health Education Authority	Take 30 minutes of moderate intensity physical activity, such as a sustained brisk walk, on at least five days of the week. Ideally these 30 minutes should be one period of sustained activity, but shorter bouts of 15 minutes are also beneficial	Killoran et al, 1994
World Health Organisation and International Federation of Sports Medicine	Adults should be encouraged to increase habitual physical activity gradually, aiming to carry out everyday at least 30 minutes of physical activity of moderate intensity. More strenuous activities could provide additional benefits	Blair et al, 1995
Centers for Disease Control and the American College of Sports Medicine	Every U.S. adult should accumulate 30 minutes or more of moderate intensity activity on most, preferably all, days of the week	Pate et al, 1995
U.S. Surgeon General's Report	An amount of physical activity sufficient to expend 150 kcals/day or 1,000 kcals/week	U.S. Department of Health and Human Services, 1996

The recommendations are so similar it would appear that there is consensus on the amount of exercise that is required in order to derive the benefits described above. However, there is much debate about this issue. Traditionally, the recommendation has been to perform exercise on 3-5 days of the week at 60-90% of maximum heart rate for

20-60 minutes per occasion. The type of activity encouraged was defined as "any activity that uses large muscle groups, is performed rhythmically, can be maintained continuously and is aerobic in nature." This type of early recommendation was primarily concerned with improving functional capacity rather than reducing the risk of chronic disease (American College of Sports Medicine, 1995). The new public health recommendations differ from more traditional ones with the emphasis on moderate intensity exercise rather than vigorous. Moderate intensity exercise has been defined as an energy expenditure equivalent to 3-6 METs (U.S. Department of Health and Human Services, 1996).

1.9 THE NATURE OF THE RELATIONSHIP BETWEEN PHYSICAL ACTIVITY/PHYSICAL FITNESS AND MORTALITY

The case for the health benefits of moderate intensity physical activity is based on the many years of epidemiological evidence. A review of this evidence suggested that there is a dose-response relationship between physical activity and mortality. It concluded that "some activity is better than none and that low to moderate intensity is better than remaining sedentary." It also acknowledged that greater amounts of activity or fitness provide greater benefits, although an optimal dose and intensity of exercise cannot be defined (Blair & Connelly, 1996). The dose response argument is not universally accepted. Some have argued that a threshold of activity is necessary to confer risk reduction, highlighting the need for more vigorous exercise (Morris, 1996). The work of Morris et al (1973, 1990) has consistently found that only vigorous physical activity is associated with a reduced risk of CHD. His data argue in favour of a minimum threshold of physical activity that needs to be exceeded before significant reductions in risk are observed.

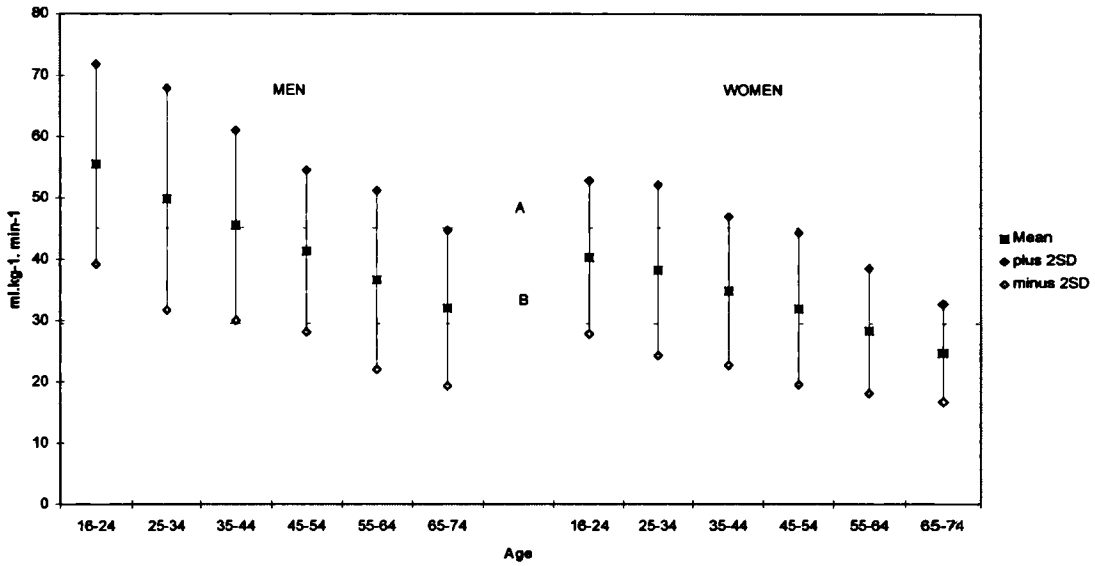
Some suggestions have been made that might explain this confusion. When comparing different studies, differences arise in the definitions of moderate and vigorous exercise. As discussed in section 1.2, it is usual in observational studies to use 'absolute' measures of energy expenditure rather then relative measures, where a given activity is assigned an exercise intensity. One problem arising from this is that different studies assign different intensities to the same activity. In the MRFIT study (Leon et al, 1987) swimming was classified as a moderate intensity physical activity yet in the work of Morris et al (1973) swimming was classified as vigorous. The MRFIT study provides evidence of a protective effect of moderate and light intensity physical activity while Morris' evidence does not show a protective effect for non-vigorous activities. In the British Regional Heart Study (Shaper and Wannamethee, 1991), which also supports moderate physical activity, golf was classified as vigorous which it was not in Morris' studies. The further problem with using absolute intensities is that for some people an activity such as walking may be a light intensity, while for others it may be vigorous depending on such factors as age, gender and initial level of fitness.

Also, the differences in populations between studies could explain some of the variation in results. Some of the studies included healthy workers while others were limited to high risk groups. It is possible that both groups differed in initial levels of fitness and thus required different amounts and intensity of exercise to improve and maintain fitness.

What may be most important in the reduction of morbidity and mortality is not total activity per se but the relative change in fitness achieved through changes in physical activity and the then level of fitness sustained over time. Men aged 45 and over and most

women would increase their fitness if they undertook moderate intensity exercise such as brisk walking (Figure 1.1 [Killoran et al, 1994]).

Figure 1.1. Average values for estimated $V0_{2max}$ by age and sex from the Allied Dunbar National Fitness Survey.



Lines A and B correspond to 45 ml.kg-^{1}. min-^{1} and 30 ml.kg-^{1}. min-^{1}. They define the range of values for aerobic fitness which would permit individuals to perform activities costing between 5 and 7.5 kcals/min. (moderate intensity) at about 50% of their $V0_{2max}$. Those whose fitness falls under line A would increase their fitness by exercising at a moderate intensity.

Before we are better able to understand the dose response relationship between total physical activity and mortality, independent of the intensity of that physical activity, we require low cost and accurate measures of relative physical activity intensity. This would allow for comparisons to be made between total energy expenditure and energy expenditure at different relative intensities. To date, the differences between studies only allow us to conclude that the majority of studies suggest that the greatest reduction in risk of CHD and all-cause mortality is seen between the least active/fit group and the next active/fit group. Although the risk is further reduced for those in higher groups the reduction in risk is smaller.

1.10 HEALTH BENEFITS OF WALKING

Most of the recommendations in Table 1.1 cite brisk walking as a good example of moderate intensity physical activity. Three large prospective cohort studies have recently highlighted the benefits of walking in both men and women. The Honolulu Heart Programme studied the relationship between walking and the incidence of CHD in 2,678 men aged 71-93 years. Men who walked less than 0.25 miles per day were at just over twice the risk of coronary heart disease compared to men who walked greater than 1.5 miles/day during the 2-4 year follow up period. (Hakim et al, 1999). Another prospective study of walking examined the risk of hypertension in 6,017 Japanese men aged 35-60 years during 59, 784 person years of follow up. The risk of hypertension in men who walked to work was 29% lower in those whose walk to work was greater than 20 minutes compared to those whose walk lasted 10 minutes or less (Hayashi et al, 1999). The Nurses' Health Study, a prospective study of 72,488 nurses aged 40-65 years with 8 years of follow examined the association between walking and the incidence of coronary events. Women who did no vigorous physical activity but walked the equivalent of 1 to 2.9 hours per week had a relative risk of CHD of 0.70 compared to women who walked infrequently, while those who walked the equivalent of 3 or more hours per week had a relative risk of 0.65. Independent of time spent walking, walking pace was an independent predictor of coronary risk. Compared with women who walked at less than 2 miles an hour (mph) women whose usual walking pace was greater than 2.9 mph had a relative risk of CHD of 0.64 (Manson et al, 1999).

These studies show that relatively low levels of what is the most prevalent of physical activities (Joint Health Surveys Unit, 1996) can lead to significant health benefits at least in most middle aged adults and the majority of older adults. A comprehensive review of the health benefits of walking proposed that national targets for walking are required and

that "middle-aged persons should be fit enough to walk 1.6km at 4.8 km/h on the level without fatigue, sore muscles, sweating or uncomfortably fast breathing" (Morris & Hardman, 1997)

1.11 SUMMARY

The health benefits of physical activity are well established even though the exact dose of exercise required to obtain these benefits is not known. Despite this, there is no doubt that a population increase in physical activity would result in substantial health benefits. Most people, particularly those middle aged and older, could achieve such health benefits through regular brisk walking which has been described as "the nearest activity to perfect exercise" (Morris & Hardman, 1997).

Chapter 2 Descriptive epidemiology of physical activity & physical fitness

2.1 INTRODUCTION

This chapter reports on cross sectional data from national surveys of adults aged 16-74 years in England. The prevalence of both physical activity and physical inactivity along with their determinants is important for shaping policy and intervention strategies. In addition to physical activity data, data on physical fitness levels will be reported.

2.2 SOURCES OF DATA AND CLASSIFICATION OF PHYSICAL ACTIVITY

Data from three main sources are presented in this chapter:

1. Health Survey for England 1994 (Joint Health Surveys Unit, 1996 [HSE])
2. General Household Survey 1996 (Thomas et al, 1998 [GHS])
3. National Fitness Survey 1990-91 (Health Education Authority and Sports Council. Allied Dunbar National Fitness Survey, 1992 [NFS])

All three surveys involved national samples and face to face interviews carried out in the persons home. The HSE interviewed 15, 809 subjects aged 16 and over, the GHS 15, 696 and the NFS 4, 316. In the NFS a subset of 2,768 subjects had their fitness measured in portable laboratories. Methods for measuring and classifying physical activity differed between surveys and are summarised below.

Physical activity can be assessed in terms of type, frequency, duration and intensity. Types of activity assessed included:

a) work activity
b) housework

c) gardening
d) walking
e) Do-It-Yourself (DIY)
f) sports and physical exercise.

All three surveys asked people about the frequency of participation in these various activities in the 4 weeks prior to the interview. The GHS asked about walking and sports/physical exercise. Gardening and DIY were asked about separately and not used in summary measures of physical activity. The HSE and NFS asked about occupational activity, housework, DIY/gardening, walking and sports and exercise. The NFS also asked about stairclimbing.

The HSE and the NFS assessed the frequency of activity by recording the number of 20 minute occasions an activity was performed in the 4 weeks prior to the interview. Occupational activity was assumed to have been performed at least 3 times per week. In the HSE all occasions of heavy housework, gardening and DIY were counted as duration of these activities was not assessed.
The GHS survey did not ask about the frequency of activities per month. It only asked if an activity had been performed at all in the previous 4 weeks and 12 months.

Duration of activity was recorded in minutes and was usually determined by asking people how long they 'usually' spent doing an activity or how long they spent on the most recent occasion. In the HSE duration was only asked regarding sports and exercise. The duration of walking was not assessed directly in any of the surveys. However 'occasions' of walking were only counted if they were 1 mile or longer in the HSE and NFS and 2 miles or longer in the GHS. In the GHS no measure of duration was included for any activities.

Intensity of activity was assessed using a combination of absolute and relative measures. In the GHS no measure of intensity was included. The HSE and NFS both assigned scores to activities placing them in rank order on a scale which reflected the effort required for an average man to carry them out. Scores were expressed in terms of kilocalories per minute (kcals/min). Variations in the intensity of activity at the individual level was taken into account by considering individual assessments of the amount of effort required to perform an activity. In the case of walking this depended on the 'usual' pace of walking, while for home activities people were given examples of types of 'heavy' housework, DIY and gardening, with participation in these activities used to classify intensity. Intensity classifications of sports and exercise were dependent on whether the person said the activity made them 'out of breath or sweaty'. The intensity of occupational activity was based on self-assessment of level of activity at work and lists of specific occupations that were known to involve greater levels of physical activity.

Intensity measures in the HSE and HFS were summarised as either 'vigorous', 'moderate' or 'light' as follows:

Vigorous	Some activity with an energy cost of 7.5 kcals/min or more.
Moderate	Some activity with an energy cost of 5 kcals/min but less than 7.5 kcals/min.
Light	Some activity with an energy cost of 2 kcals/min but less than 5 kcals/min. Only sports, exercise and occupational activities could be classified as vigorous.

2.3 SUMMARY MEASURES

Most physical activity surveillance tools combine measures of frequency, duration and intensity to produce summary measures of total physical activity levels.

As the GHS does not enquire about frequency of physical activity and does not include gardening and DIY in summary measures of physical activity, only data from the HSE and the NFS will be used to describe population levels of physical activity. GHS data will be included in the section on population trends and walking levels

The HSE and NFS use a summary measure incorporating elements of frequency, duration and intensity of occupational, household, gardening/DIY, walking and sport/recreational physical activity. The reference period was the 4 weeks prior to interview.

Level 5	Twelve or more occasions of vigorous activity
Level 4	Twelve or more occasions of a mix of moderate and vigorous activity
Level 3	Twelve or more occasions of moderate activity
Level 2	Five to eleven occasions of at least moderate activity
Level 1	One to four occasions of at least moderate activity
Level 0	No occasions of moderate activity

In the HSE sports and exercise occasions were only counted if they lasted for at least 20 minutes whereas in the NFS these plus home activities were only counted if they lasted 20 minutes.

Physical fitness was only measured in the NFS and included measures of:

a) shoulder flexibility
b) handgrip strength
c) leg strength
d) leg power
e) aerobic capacity

Only data on aerobic capacity will be presented in this report as this measure of physical fitness is most related to the mortality data presented in Chapter 1. Aerobic capacity was measured by means of a sub-maximal treadmill test developed specifically for the NFS (Allied Dunbar National Fitness Survey, 1992 pp 18). The results of the tests were reported as oxygen uptake relative to body mass expressed as millilitres of oxygen per kilogram bodyweight per minute (ml O_2/kg/min)

The proportion of adults active at different levels are shown from the NFS and the HSE in Figures 2.1- 2.6.

Figure 2.1 shows that 33% of men and 34% of women were taking, on average, no more than one 20 minute occasion of at least moderate intensity physical activity per week. More women were active at a level 3, moderate only, compared to men, but more men were active than women at levels 4 and 5 where vigorous intensity activity is introduced. The picture is slightly different in the HSE where men are more active than women from level 3 onwards (Figure 2.2).

Figure 2.1 Proportion of men and women aged 16-74 in activity levels - NFS 1990-91

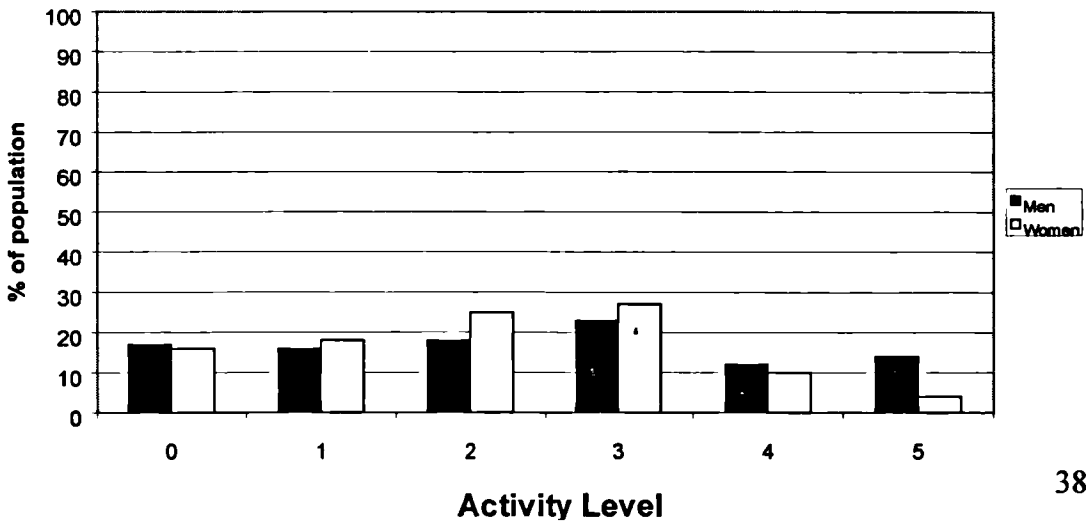
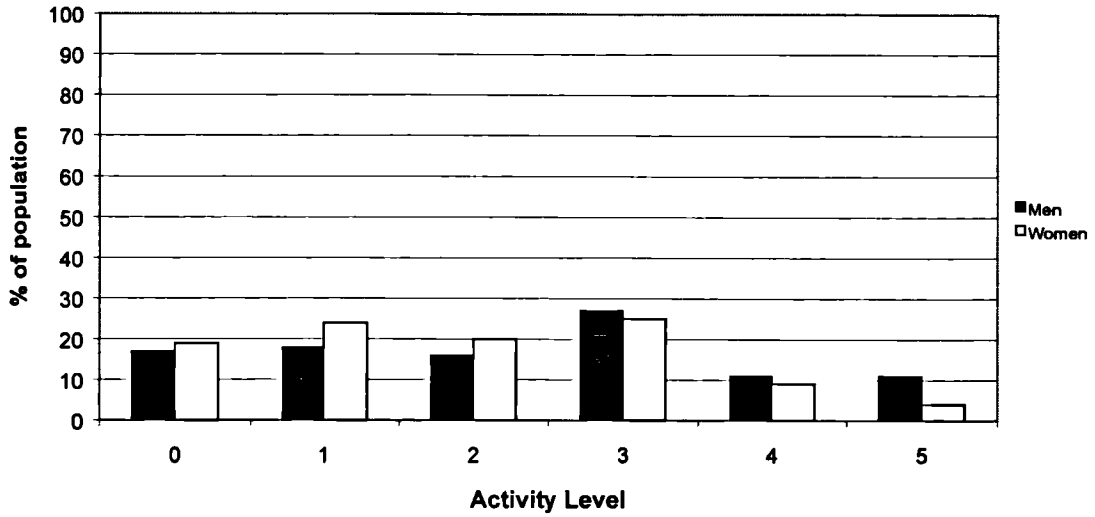


Figure 2.2 Proportion of men and women aged 16-75+ in activity levels - HSE 1994



The proportions of men and women who are inactive (level 0) increases with age with a marked change in the age group 55-64 for both men and women (Figures 2.3, 2.4). In 1994, 58% of men and 64% of women aged 55 years and over were taking, on average, less than one 20 minute occasion of at least moderate intensity physical activity per week (Figures 2.5, 2.6). Data from both surveys show a steep decline in activity levels 4 and 5 with age (Figures 2.3 - 2.6).

Figure 2.3 Proportion of men active at different levels by age - NFS 1990-91

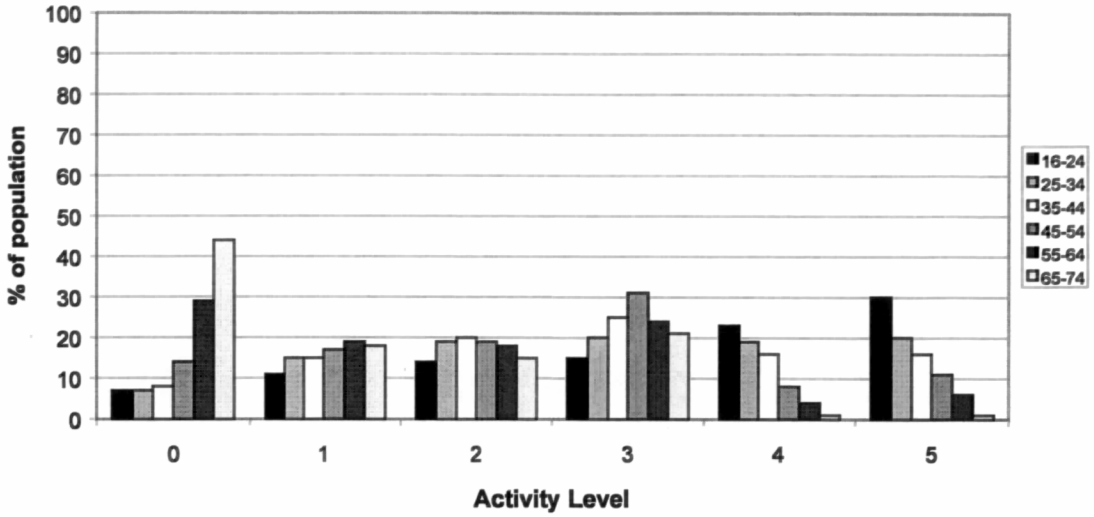


Figure 2.4 Proportion of women active at different levels by group - NFS 1990-91

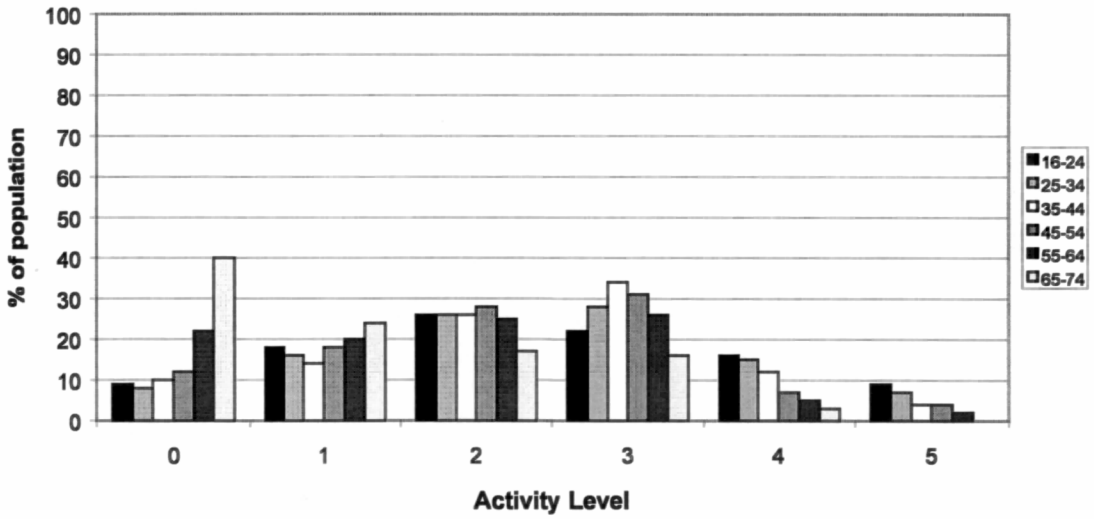


Figure 2.5 Proportion of men at different activity levels by age group - HSE 1994

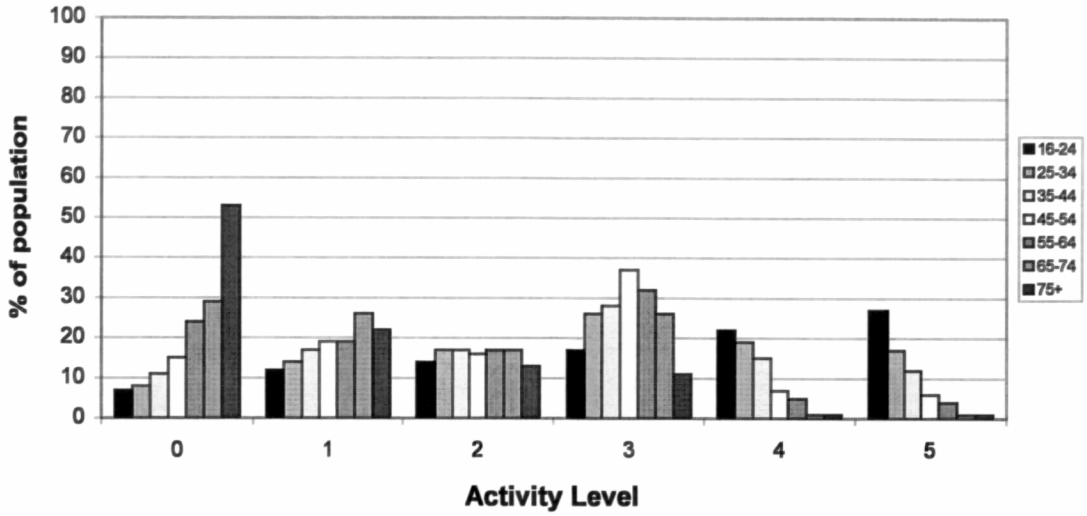
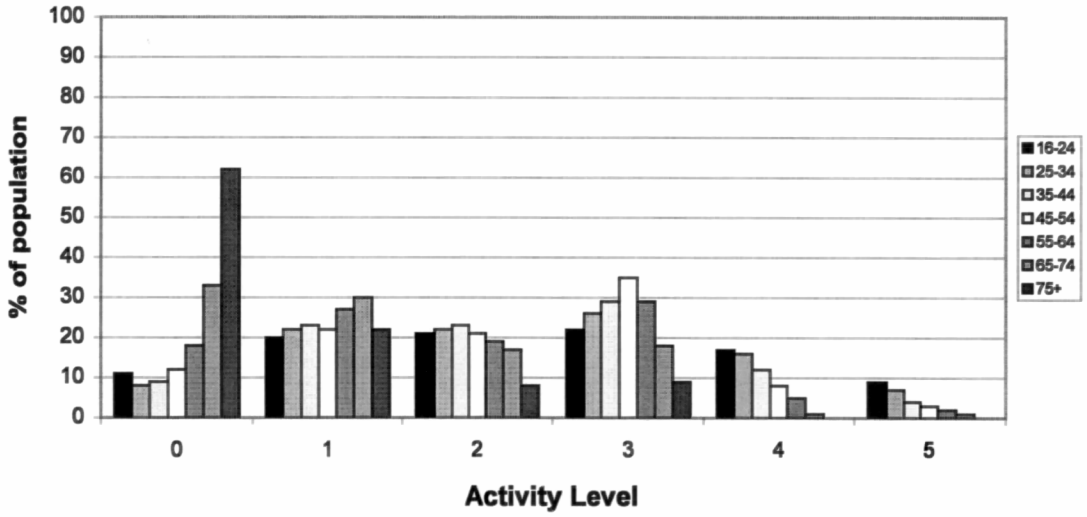


Figure 2.6 Proportion of women at different activity levels by age group - HSE 1994



Although it is not possible to state the exact dose of physical activity required to obtain the reductions in mortality described in Chapter 1, the authors of the NFS estimated an optimal threshold level of physical activity that people at different ages should strive for. The suggested target thresholds are shown in Table 2.1. It should be remembered that the targets were proposed prior to the current international recommended amounts of physical activity.

Table 2.1 Proposed Target Thresholds for Physical Activity

Age group	Men	Women
16-34	Activity Level 5	Activity Level 4 and above
35-54	Activity Level 4	Activity Level 3 and above
55-74	Activity Level 3	Activity Level 3 and above

The percentage of men and women who fall below these thresholds are shown in Table 2.2

Overall 74% of men and 68% of women were below their optimum physical activity level. Major differences between men and women exist in the age band 35-54 years.

Table 2.2 Proportion of men and women below physical activity threshold by age group

	Men	Women
Age group	%	%
16-24	70	75
25-34	80	78
35-44	68	50
45-54	81	58
55-64	66	67
65-74	77	81

2.4 PROPORTION OF ADULTS ACTIVE AT RECOMMENDED LEVELS AND THOSE WHO ARE SEDENTARY

Both the NFS and the HSE reported the frequency of 20 minute periods of both moderate and vigorous intensity physical activity. The 20 minute bouts do not easily allow for comparisons to be made between nationally recommended amounts of physical activity and actual physical activity. However, data is also available on 30 minute occasions of moderate intensity for both the NFS and the HSE (Fentem & Walker, 1995; Joint Health Surveys Unit, 1996). The results from both surveys are similar (Table 2.3). The difference in moderate levels for men in the two surveys may be explained by the estimate of duration in the HSE. The duration of each occasion of heavy housework, gardening, DIY

reported was not assessed but was assumed to have lasted at least 30 minutes, possibly resulting in an overestimate of this type of activity.

Table 2.3 Adults aged 16-74 who are active at recommended levels or who are sedentary

	HSE 1994		NFS 1990-91	
	Men	Women	Men	Women
	%	%	%	%
Active at a vigorous level*	12	4	14	4
Active at a moderate level†	39	24	36	24
Sedentary†	27	31	29	28

*May also be active at a moderate level; † Mutually exclusive groups

Both studies show that just under 30% of men and women are sufficiently inactive to put their future health at risk. Figures 2.7 and 2.8 show how the proportion of sedentary people increases sharply with age.

Figure 2.7 Proportion of adults with a sedentary lifestyle by gender and age group - NFS 1990-91

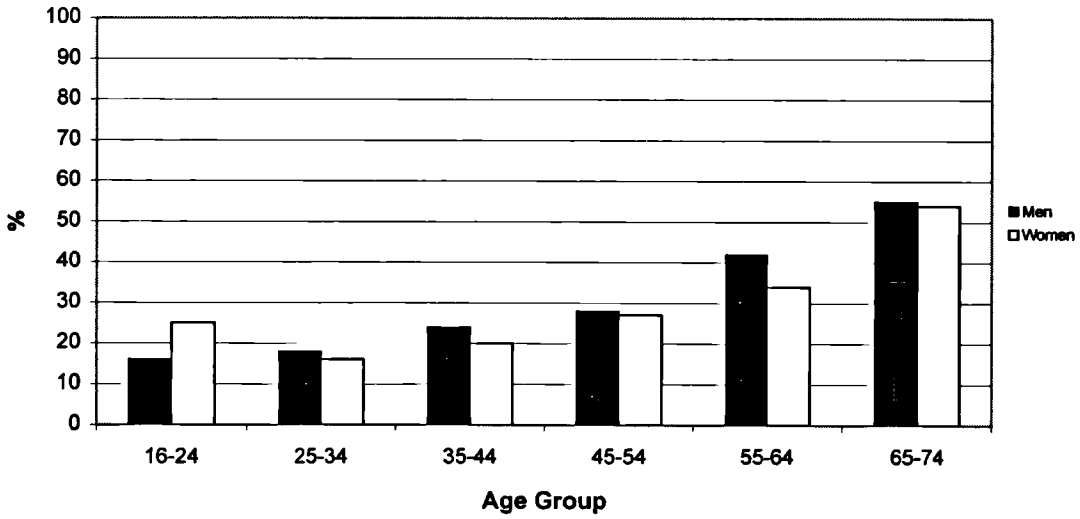
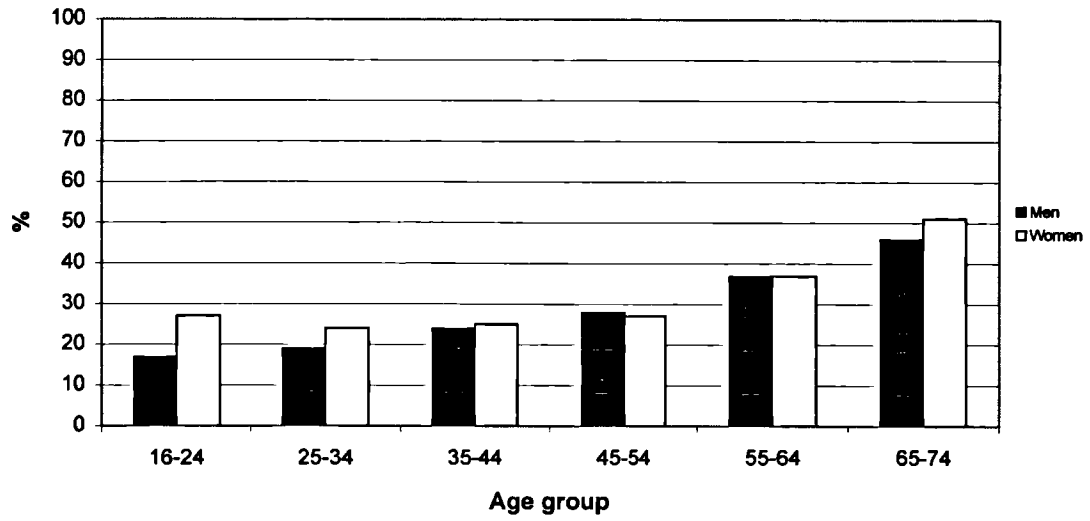


Figure 2.8 Proportion of adults with a sedentary lifestyle by gender and age group - HSE 1994



Approximately half of adults aged 65-74 years are sedentary. In both surveys the biggest difference between men and women is in the age group 16-24, where 9% more women than men in the NFS and 10% more in the HSE are sedentary.

2.5 VARIATIONS IN PHYSICAL ACTIVITY BY SOCIAL CLASS

Tables 2.4 and 2.5 show levels of physical activity by social class. Results from the HSE show that regular moderate and vigorous physical activity is more prevalent in social classes IV and V and yet inactivity (level 0) is also more prevalent in those groups (Table 2.4). Data from the NFS show how inactivity increase with decreasing social class particularly for women (Table 2.5).

Table 2.4 Age standardised proportions of physical activity level by own social class - HSE 1994

	Social class groups			
	I and II	IIINM	IIIM	IV and V
Activity levels 3,4, and 5				
Men	46	45	54	55
Women	40	34	41	42
Activity Level 0				
Men	14	14	18	19
Women	17	19	21	20

Table 2.5 Levels of inactivity by social class - NFS, 1990-91

	Men	Women
Age group 16-34	%	%
Social class I and II	6	6
IIINM	7	7
IIIM	9	10
IV & IV	6	14
Age group 35-54		
Social class I and II	9	9
IIINM	8	13
IIIM	13	10
IV & IV	14	16
Age group 55-74		
Social class I and II	31	28
IIINM	40	33
IIIM	38	31
IV & IV	36	32

2.6 TRENDS IN PHYSICAL ACTIVITY

Data on physical activity is available from the 1991-1994 Health Surveys allowing for comparisons of physical activity over time. Between 1992 and 1993 questions relating to housework changed resulting in a lower proportion of people being classified in level 3 and above.

Overall there were no changes in those active at level 3 and above for men, but for women there was a 4% decline. However, the changes to items relating to housework

may account for this (Table 2.6). Within each age band, changes do exist. Men aged 16-24 years showed a 4% increase while men aged 75 years and over showed a 5% decline. For women the largest change was observed in the age group 45-54 years, declining from 57% in 1991 to 45% in 1994.

Table 2.6 Proportion of adults active at level 3 and above 1991-1994 by gender and age group

		Age Group						
	All	16-24	25-34	35-44	45-54	55-64	65-74	75+
Men								
1991	49	63	59	53	53	41	33	13
1992	48	69	61	49	45	45	24	18
1993	47	67	58	51	47	38	24	16
1994	49	67	62	55	50	40	28	12
Women								
1991	42	52	51	45	57	43	22	10
1992	41	48	48	55	47	39	23	10
1993	36	43	42	45	43	35	22	8
1994	38	47	49	45	45	36	20	9

From 1987 to 1990 there was a 3% increase in participation in sport from 45%-48%. However, from 1990-1996 participation has declined from 48% of adults in 1990 to 46% in 1996 (GHS, 1996). Only cycling has shown an increase in participation, up 8% since 1987. For women, there is no significant difference in participation rates between 1990 and 1996, 38% and 39% respectively yet for men in the same period rates declined from 58% to 54%.

2.7 PARTICIPATION IN WALKING

In 1990-91 over half of both men and women of all age groups reported walking at least once in the past week for a mile or more. However, this figures drops by more than 50% when the criteria includes walking pace. Just 26% of men and 21% of women walked for a mile or more at a brisk/fast pace at least once in past week. The proportion walking at this pace declined with age for both men and women much more sharply than all walks combined (Table 2.7).

Table 2.7 Proportion of men and women who walked continuously for a mile or more in the past week on at least one occasion by age group - NFS, 1990-91

Age groups	Pace of walks		
	All walks	Average/slow paced walks	Brisk/fast paced walks
Men			
16-34	58	22	36
35-54	54	27	27
55-74	53	39	14
Women			
16-34	58	34	24
35-54	55	32	23
55-74	51	34	17

The HSE reports on the proportion of adults walking a mile or more at least 3 times a week at a brisk or fast pace in the last 4 weeks. Thirty one percent of men and twenty two per cent of women reported walking at this level in 1994. Again these proportions decline with age in both men and women, going from 47% of men aged 16-24 years to 15% of men aged 65-74. In women, the rate reduces from 31% of women aged 16-24 years to 11% aged 65-74 years.

The GHS enquired about walks of 2 miles or more. Forty nine per cent of men and forty one per cent of women reported at least one 2 mile walk in the last 4 weeks. In the period from 1987-1996 this type of walking had increased from 38% in 1987 to 45% in 1996. In

the HSE walking levels of all adults between 1991 and 1994 remained relatively unchanged. However, men over the aged of 45-64 showed a 6% increase in walking levels during this time period even though women did not.

Data from the National Travel Survey, an annual household survey of personal travel habits, reveals that the number of walking journeys as a percentage of all journeys has fallen from 35% in 1975/76 to 29% in 1994/96. Also, in 1975/76 the average distance walked represented 5% of the total travelled which has now fallen to 3% (DETR, 1998).

Although the GHS shows an increase in the number of people reporting at least some walking in the last 10 years, it is possible that the total amount of time spent walking has in fact decreased over the last 20 years. A striking finding in the travel survey data is that in 11-15 year olds the number of walking trips fell by 29% from 1985/86 to 1994/96.

2.8 AEROBIC FITNESS

The NFS conducted sub-maximal treadmill tests on a subset (1,741) of subjects who were interviewed. To make interpretation of the results easy, the authors reported levels of fitness in terms of a person's capacity to perform different levels of walking. Table 2.8 shows the capacity to walk at 3 miles per hour (an average walking pace) up a 5% gradient. Exceeding the threshold of 70% of maximal heart rate would require 'severe exertion'. The results show a marked difference between men and women particularly in the younger age groups. Nearly half of all women over the age of 25 and over 90% of women aged 55 years and older would find walking at an average pace on a slight incline a significant physical challenge. Also, 49% of women aged 55-64 would require severe exertion to walk 3 miles per hour on the level (not shown).

Table 2.8 An estimate of the proportion of adults exceeding 70% of maximal heart rate walking up a 5% gradient by age group and gender - NFS, 1990/91.

	Men	Women
Age group	%	%
16-24	4	34
25-34	11	49
35-44	23	68
45-55	43	81
55-64	70	91
65-74	81	92

2.9 SUMMARY

Physical inactivity or sedentary living level is prevalent in both men and women and increases markedly with age. Between 40%-45% of adults aged 65-74 engage in such small amounts of physical activity as to put their health at risk and significantly influence the quality of their life.

Only about 50% of all adults are active at least 3 times per week and even fewer are exercising at recommended levels. Since 1991 physical activity levels have changed little. Although walking is the most popular physical activity, people should be encouraged to walk for longer and at a brisker pace.

The low levels of physical activity are reflected in the poor levels of fitness. In women, fitness levels are so low that even walking for transport is a major physical challenge for the majority of women aged over 55 years.

The relative risk of CHD for the least active is similar to that of smoking and the prevalence of both behaviours is similar. Thus, physical inactivity represents a major public health problem. It has been estimated that the incidence of coronary heart disease

and hypertension could be reduced by up to 32% if those who were sedentary became active (Nicholl et al, 1994).

Chapter 3 Systematic Review of Physical Activity Interventions

3.1 INTRODUCTION

Although a large body of evidence exists about the health benefits of physical activity, far less is known about the effectiveness of strategies to achieve the increases in physical activity believed to be necessary to acquire these benefits.

A number of systematic reviews already exist with each highlighting the infancy of research into this area (King et al, 1992; Dishman & Sallis, 1994; Dishman & Buckworth, 1996; Hillsdon & Thorogood, 1996, Blair & Morrow, 1998) . They have shown that there are multiple influences on physical activity behaviour at intrapersonal, interpersonal, social, environmental and programme levels. Table 3.1 summarises the main positive and negative determinants of leisure time physical activity. It should be remembered that most studies are from North America and therefore these determinants may not transfer to British populations. The definitive list of ingredients for an intervention most likely to lead to significant changes in physical activity has yet to be discovered. It is likely that a different mix of determinants exist for different populations.

Table 3.1 Main determinants of leisure time physical activity*

Determinant	Repeated negative association with physical activity	Repeated positive association with physical activity
Age	✓	
Gender (male)		✓
Education		✓
Socio-economic status		✓
Ethnicity (non-white)	✓	
Barriers to exercise	✓	
Exercise enjoyment		✓
Expect benefits		✓
Intention to exercise		✓
Mood disturbance	✓	
Perceived health or fitness		✓
Self-efficacy		✓
Self-motivation		✓
Stage of change		✓
History of physical activity		✓
Social support		✓
Climate (cold)	✓	
Perceived effort (high)	✓	

* Adapted from Sallis & Owen (1999)

Due to the heterogeneity of studies, most reviews to date have been narratives. The only meta-analysis found that effect sizes were greater when principles of behaviour modification were used; specific groups were targeted; the exercise intensity was low; the intervention was delivered via the post or the telephone; the population was apparently healthy and when the goal of the intervention was to increase leisure physical activity (Dishman & Buckworth, 1996).

In this chapter I report a revised and updated version of a systematic review of randomised controlled trials of physical activity promotion in apparently healthy, free-living adults. This review has previously been updated twice and published 3 times (Hillsdon et al, 1995; Hillsdon & Thorogood, 1996; Hillsdon et al, 1999). The aim of the

chapter is to provide recent and reliable information on the effectiveness of physical activity promotion.

There are randomised, controlled trials using exercise as an intervention to study the physiological effects of exercise and in the management of health problems, notably hypertension, hyperlipidaemia and overweight. These show the effects of exercise on various physiological and biological outcomes and demonstrate the importance of exercise in the management of disease. However, because the main outcomes of such trials is not physical activity, they do not help us understand the effectiveness of physical activity promotion strategies. For these reasons I did not consider them for this review.

3.2 METHODS

Computerised searches were carried out using Medline, Embase, Amed, PsychLit, Sport and SCISearch from 1966-1999. The method described by Dickersin and colleagues (1995) was used to search for randomised controlled trials on Medline with additional guidance from John Eyres (LSHTM librarian) an expert in searching electronic databases. Key words for searching included 'exercise', 'physical activity', 'Randomised-Controlled-Trial'and 'Randomized-Controlled-Trial'. The search was limited to English language journals. Additional searching was carried out using the references from both existing reviews (King et al, 1992; Dishman & Sallis, 1994; Dishman & Buckworth, 1996; Hillsdon et al, 1999) and the papers identified during the search. In addition to the studies described in Hillsdon & Thorogood (1996) a further 7 were found. Those studies included in the previous review were re-read by two of us (myself plus Margaret Thorogood) independently as were the new studies identified during this search. Each

paper was read and assessed using a shortened version of the EPI-Centre Review Guidelines (1996).

The criteria for inclusion of trials in the review were:

- a control group;
- subjects assigned to control or intervention by a process of randomisation;
- trials testing single factor interventions to increase activity;
- interventions tested on apparently healthy, free living adults;
- minimum of 12 weeks duration;
- exercise behaviour was the dependent variable;

3.3 RESULTS

Nineteen trials met the inclusion criteria and are described in Tables 3.2 and 3.3 (studies 5 and 6 are from the same paper and are reported separately for convenience). Most of the trials were from the USA with 3 from England (studies 11, 18 & 19) and 1 from Australia (study 8). Subjects were mainly white, middle aged and well educated. Most subjects were volunteers, recruited via local advertisements. The trials include an even mix of males and females with an age range of 18-74 (mean of approximately 49).

Table 3.2a. Summary of interventions - home based

Study	Authors, Year of Publication, Stated Objectives	Length of Intervention	Location of exercise	Authors Description of Exercise	Prescribed Frequency, Intensity & Duration of Exercise	Controls
1	Kriska, 1986 -To examine factors associated with exercise compliance in post menopausal women	2 years	Home following initial 8 weeks	Walking	3 x wk/ 3 miles per session briskly	Assessment only
2	Lombard, 1995 -To determine the effect of frequency and structure of telephone prompts on frequency of walking	12 weeks	Home	Walking(group walking encouraged)	3 x wk at least 20 minutes per session	Initial instruction
3	King, 1991 -To determine the effectiveness of group vs. home based training of higher and lower intensities	1 year	2 groups home, 1 group facility	Walking and jogging	Two groups 3 x wk at 73-88% peak heart rate for 40 min. per session, one group 5 x wk at 60-73% peak heart rate for 30 min. each session	Assessment only
4	Noland, 1989 - To assess effects of behavioural techniques on adherence to unsupervised exercise	18 weeks	Home	Walking, jogging and swimming as preferred	3 x wk at 30-40% or 60-70% VO_2 max. for 30 minutes	Assessment and advice about exercise; no behavioural treatment
5	King, 1988 - To evaluate strategies for enhancing the maintenance of exercise training by healthy middle aged men and women (also see number 6)	6 months	Home	Walking and jogging	4 x wk at 65-77% peak heart rate for 30 minutes per session	Same as intervention group but reduced level of self monitoring
6	King, 1988 - To evaluate strategies for enhancing the adoption of exercise training by healthy middle aged men and women (also see number 5)	6 months	Home	Walking and jogging	4 x wk at 65-77% peak heart rate for 30 minutes per session	Same as intervention group less regular telephone contact
7	Godin, 1987 - To investigate the effectiveness of fitness testing and health appraisal on exercise intention and behaviour	3 months	Home	Physical activity lasting 20-30 minutes per session	None prescribed	Assessment only
8	Bull, 1998 - To test the effectiveness of verbal advice on exercise from a family physician, plus written materials, in a primary health care setting	2-3 minutes advice	Participants choice	Not stated	Moderate intensity leisure time	Assessment only + written materials
9	Chen, 1998 - To evaluate a minimal behavioural intervention program designed to promote walking among initially sedentary ethnic minority women	8 weeks	Home	Walking	Individually determined	Brief phone call + educational materials
10	Marcus, 1998 To compare the effectiveness of a motivationally tailored and standard self help materials for physical activity adoption	6 months	Home	Moderate intensity	Not prescribed but focus on 5 x wk, 30 minutes	Standard self help materials via the post
11	Harland, 1999 - To evaluate the effectiveness of combinations of three methods to promote physical activity	2-12 weeks	Participants choice	National recommendations for age	Individually negotiated	Fitness test + written information

Table 3.2a continued

12	Goldstein, 1999 - To test the efficacy of a brief physician counselling session compared to usual care on self reported physical activity	5 minutes	Home	Moderate intensity	Individually negotiated	Standard care

Table 3.2b Summary of interventions - facility based

Study	Authors, Year of Publication, Stated Objectives	Length of Intervention	Location of exercise	Authors Description of Exercise	Prescribed Frequency, Intensity & Duration of Exercise	Controls
13	McAuley, 1994 - To determine the utility of an efficacy based intervention on exercise participation	20 weeks	Facility	Walking	3 x wk, 40 minutes	Initial instruction + exercise information classes
14	King, 1984 - To study the effect of two low cost methods of increasing the number of participant controlled jogging episodes	5 weeks	Facility	Jogging	4 x wk, individualised time and distance goals	Instructed to jog alone
15	MacKeen, 1985 - To study the effects of an 18 month exercise intervention on adherence.	18 months	Facility and Home	Jogging, swimming, games	3 x wk minimum, 35-75 minutes per session	Assessment only
16	Reid, 1979 - To assess the effectiveness of physician prescribed exercise programme with health education and self monitoring components.	1 hour	Facility	Endurance activity	Advice about frequency, intensity, duration given but not described	Assessment and written exercise advice
17	Marcus, 1993 - To assess effectiveness of a relapse prevention programme and reinforcement programme in increasing exercise adherence and short term maintenance	18 weeks	Facility	Exercise to music class	35-50 minutes 3 x wk	Attendance at exercise group, no behavioural technique
18	Stevens, 1998 To assess the cost effectiveness of a primary care based intervention aimed at increasing physical activity in inactive people aged 45-74	10 weeks	Facility + home	Subjects choice after discussion of options	Increase current activity	Educational materials
19	Taylor, 1998- To examine the effects of a GP exercise referral scheme on modifying physical activity and other CHD risk factors	10 weeks	Facility	20 exercise sessions at facility up to one hour each time	2 sessions per week up to 60 minutes	Waiting list

Table 3.3a Summary of results - home based

Study	Data analysed by 'intention to treat'	No. In Study	Subjects	Post Intervention Follow Up	Actual Frequency, Intensity & Duration of Exercise Intervention Group	Main Outcomes p<0.05	Outcome + or 0
1	Yes	229	Post menopausal women aged 50-65	annually	Mean miles walking /wk = 8.4	Self reported walking level significantly higher at years 1 & 2 compared to controls.	+
2	Yes	135	University staff and faculty members, mean age 40, mainly female	12 weeks	46% of frequent prompt groups walking 3 x 20 minutes per week; 13% of low frequency prompts; 4% controls	Frequent telephone contact improved adherence to walking programme	+
3	Yes	357	160 women and 197 men aged 50-65. Predominantly white and well educated.	on-going	Mean frequency = HIG ~ 1.2 x wk, HIH ~ 2 x wk, LIH ~ 3 x wk	Significant difference between intervention and control groups plus significant difference between home based and facility based groups.	+
4	No	77	28 men (mean age 40) and 49 women (mean age 36)	nil	Self monitoring group = mean of 2.4/week for 26 mins. Reinforcement group = mean of 2.5/week for 29 mins.	Behavioural interventions increased frequency of exercise compared to controls	+
5	Yes	51	male and female middle aged subjects	nil	11.4 sessions/month for daily self monitoring group; 7.5 sessions/month for weekly self monitoring group	Significant difference in number of exercise sessions/month between groups	+
6	Yes	52	male and female middle aged subjects	nil	12.4 sessions/month for 32 minutes in telephone group; 9.8 sessions/month for 28 minutes in comparison group	No significant difference in mean number of exercise sessions/month between groups. Both groups increased exercise frequency over baseline	0
7	No	200	Average age 39 (± 9)	nil	~ 2-3 sessions/month	No significant difference between groups	0
8	Yes	763	Adults (aged 18-60+) attending health centre	12 months	33.1% 'exercising' ≥ 5 hours in previous 2 weeks	No significant difference between groups	0
9	Yes	125	Ethnic minority women aged 23-54	30 months	57 mins.walking/week in behavioural group; 53 mins. walking/week education group.	No significant difference between groups	0
10	No	194	Healthy sedentary men and women (76%) average age 44	nil	151 mins of physical activity/wk in motivation gp; 98 mins/wk standard gp	Significant between group difference	+
11	No	523	Sedentary men and women aged 40-64	1 year	20% increased sessions of vigorous activity and 22% increased sessions of moderate activity	No significant difference between groups	0
12	No	355	Healthy men and women (65%) mean age 65.9 (SD 9.1)	8 months	28% meeting recommended amount; either 3 x 20 mins vigorous per week or 5 x 30 mins moderate per week	No significant difference between groups	0

+ = positive significant difference; 0 = no significant difference

Table 3.3b Summary of results - facility based

Study	Data analysed by 'intention to treat'	No. In Study	Subjects	Post Intervention Follow Up	Actual Frequency, Intensity & Duration of Exercise Intervention Group	Main Outcomes p<0.05	Outcome + or 0
13	Yes	125	Previously sedentary, 45-64 year olds	None	Not stated	Intervention subjects exercised more frequently and for longer than controls	+
14	Yes	58	18-20 year old previously sedentary female psychology students	2 months	Mean frequency JAR and G =2.4/week;GR−1.4/week	83% of jogging alone + relapse subjects still exercising at follow up compared to 36% of control subjects.	+
15	No	171	Males aged 40-59 with CHD risk factors	12 years	Mean hours jogging/week at year 13 = 0.3 hours	No difference between exercise and control conditions at follow up on jogging hours per week.	0
16	No	124	Male firefighters aged 24-56	6 months	Not stated	No significant difference between groups	0
17	Yes	120	Previously sedentary, female university employees with a mean age of 35 years	2 months	Percentage of classes attended during the 18 weeks RP = 51%, R = 49%, Controls = 44%	No significant difference in attendance at 18 weeks or 2 month follow up.	0
18	Yes	714	45-74 year olds from 2 urban health centres	8 months	6 occasions of mod/vig exercise in previous 4 weeks	10.6% reduction in number of intervention subjects classed as sedentary	+
19	No	142	40-70 year olds from 2 health centres	9 months	9.1 gym attendances /10 wks	No between group differences in energy expenditure at 37 weeks	0

HIG high intensity group; HIH high intensity home; LIH = low intensity home; JAR = jogging alone + relapse prevention; G = group jogging; GR = group jogging + relapse prevention; RP relapse prevention; R reinforcement

Interventions

Table 3.2 summarises the main exercise components of the trials and Table 3.3 the results. Both tables are sorted by location (home or facility) of exercise and then by outcome. Intervention periods ranged from 5 weeks to 2 years. Thirteen of the trials included post intervention follow up periods which ranged from 2 months to 12 years. Eleven of the nineteen studies analysed outcomes on an intention to treat basis. In the trials, subjects were asked to exercise between 3-5 times per week for 20-60 minutes. Only limited information was provided on the intensity of exercise advised and completed, but in general there was a mixture of moderate and vigorous intensities. Studies published during the last 2 years gave greater emphasis to moderate intensity physical activity.

Location of exercise - The location of the prescribed exercise was the home for 12 of the trials (Table 3.2a). By home location we refer to exercise that can take place in proximity to the subjects' homes rather than within their homes. Six out of the 12 home based trials (studies 1-5,10) reported a positive outcome of the intervention. One of the trials, study 6, not showing a significant difference between groups was a comparison between subjects receiving telephone contact and those not receiving it. All of the subjects were sedentary at baseline and significantly increased their exercise level during the intervention. Those subjects receiving telephone support exercised more than those who did not but the difference did not reach significance.

Of the seven facility based trials, two included a mix of facility and home exercise (15, 18). Facility based trials normally required subjects to attend at least some specific

sessions or groups at a local fitness centre or indoor track. Three of the seven facility based trials showed a significant difference between intervention subjects and controls.

Study 3 compared home based and facility based exercise. After one year, subjects assigned to the two home based arms completed significantly more of the prescribed exercise sessions than subjects assigned to exercise at a facility (79%, 75 % and 53% respectively), with no significant difference between the two home based arms. A significant contribution to this discussion has been made by Project Active, a large randomised (not controlled) trial which has shown that significant improvements in physical activity, fitness and other cardiovascular risk factors can be achieved without the need to attend supervised, structured physical activity (Dunn et al, 1999).

Components of prescribed exercise – Six of the 8 trials which stated walking as the prescribed mode of exercise showed a significant increase in exercise when compared to controls. In one study (study 1), 80% of subjects were walking an average of at least 5 miles per week with 61% of subjects adhering to the prescribed level of 7 miles per week at 2 years. In a 10 year follow up of the same trial, intervention subjects were still walking significantly more than controls (Perieira et al, 1998). The trials in which walking was not specifically recommended included exercise to music classes, gym based 'endurance activity', jogging and self-determined activity. Three of the trials that did not specifically refer to walking showed an increase in exercise (10,14,18). In one of the studies (14) subjects were females aged 18-20, who may have tolerated the prescribed jogging better than the older groups in the other trials Study 18, which offered subjects the opportunity to attend a local facility at reduced cost, showed increases in physical activity not

explained by attendance at the facility. Significant changes were only observed in moderate intensity activity suggesting that unstructured modes of activity were preferred in those subjects.

Although the prescribed frequency of exercise averaged 3-5 times per week, most subjects were reporting lower frequency at follow up, with an average 2-3 times per week. Study 3 assigned subjects to three intervention arms of varying frequencies. One of the two home based arms prescribed 3 sessions per week for 40 minutes at a high intensity, while the other home-based arm prescribed 5 sessions per week at a low intensity. The third arm, where subjects exercised at a local community hall prescribed 3 sessions per week. At one year there was no significant difference between the two home based arms on the percentage of prescribed sessions completed, with both completing significantly more than subjects in the facility based arm. Second year follow up data (King et al, 1995) show that subjects in the 3 times per week home based arm were able to maintain significantly higher levels of adherence than those in the 5 times per week home based arm who had reduced to a level similar to that of the facility based arm (68%, 49% and 36% of prescribed sessions respectively). Although the two home based arms were prescribed differing intensity levels, analysis of heart rate data showed that both arms actually exercised at an intensity normally described as moderate. Studies 10 and 18 were both able to show changes in the frequency of moderate intensity exercise. Study 18 which reported both moderate and vigorous, did not show any significant increases in the frequency of vigorous intensity exercise. Study 11, showed changes in vigorous activity similar to those in moderate although the differences over baseline were not significantly different from controls.

Strategies for improving compliance - A range of behavioural methods were employed to improve compliance. It is difficult to measure the effect of some of these as they were often part of multi-faceted interventions taught to all groups. Methods included reinforcement (rewarding subjects for successful completion), self-monitoring (keeping personal records of exercise performed) and relapse prevention training (learning to cope with situations that prompt inactivity and preventing a missed session leading to a return to pre-intervention exercise levels). Some trials investigated the impact of such strategies with varying results. In study 4 subjects were randomly assigned to self-monitoring, reinforcement and control arms. After 18 weeks subjects in the two behavioural treatment arms were exercising significantly more than those in the control arm. Study 16 found no difference in exercise levels between subjects instructed in self-monitoring and control subjects. Study 5 took subjects from an earlier trial and randomised them to two 'maintenance' groups with different frequencies of self-monitoring. Subjects completing daily self-monitoring forms performed 35% more exercise sessions than subjects completing forms weekly.

Relapse prevention training was compared with reinforcement strategies in a study of females attending exercise classes (study 17). Subjects in the relapse prevention arm attended weekly lessons on relapse prevention immediately following an exercise class, while subjects in the reinforcement group received T-shirts and other rewards for successful attendance at a number of classes. Control subjects simply attended the exercise classes. At 18 weeks there was no difference between groups on number of exercise sessions attended with 72% of subjects attending less than the prescribed 3 classes per week.

In a trial of jogging alone or in a group, and of jogging with and without relapse prevention training (study 14), the impact of relapse prevention varied. Eighty three per cent of subjects (10 of 12) with relapse prevention training who were jogging alone, were still exercising at 3 months compared with 36% (5 of 12) of those without such training. By contrast, in the two group jogging arms relapse prevention training did not increase jogging frequency at follow up.

Study 3 investigated the effect of subjects' perceptions of whether they had achieved expected physical or psychological benefits after 6 months on subsequent exercise adherence (Neff et al, 1995). Those subjects who reported they had achieved expected benefits completed more exercise sessions in the next 6 months than those who did not achieve their expectations. It seems that to maintain adherence in the long term, subjects need to perceive a physical or psychological gain from exercise.

Studies 8 and 10 produced computer generated tailored reports based on data collected from baseline questionnaires. Study 10 showed significant differences in physical activity at 6 months in the tailored group compared to those receiving standard self help materials. Study 8 did not show any differences at 12 months follow up although there were differences at earlier stages.

Follow up - Telephone calling was a common method for following up clients in home based trials after an initial instruction session. All of the home based trials, apart from one (study 9), where researchers maintained contact with clients by telephone, reported positive outcomes. Subjects in study 9 were women from ethnic minorities who may not have welcomed telephone support in the same way that middle income, white populations

might. Also, the study reported difficulty in making contact via the telephone with difficulty completing the first telephone contact being a predictor of study dropout. Studies 2 and 6 investigated the effect of telephone prompting. Study 2 randomised subjects to four levels of telephone prompting or to a control arm. All subjects received 15 minutes of instruction on walking. At 6 months there was a significant difference in numbers of subjects still walking between the three prompted arms and the control arm, and between prompt frequency (once per week versus once every three weeks). Study 6 randomly assigned subjects who were waiting list controls from a previous trial (Juneau et al. 1987), to two interventions, one of which received telephone contact (10 times during 6 months). All subjects received instructions in behavioural methods to improve compliance. Subjects in the telephone prompting arm exercised more frequently and for longer than those in the control arm (12.4 sessions/month for 32 minutes versus 9.8 sessions/month for 28 minutes). This difference did not achieve significance. Only subjects in the telephone arm significantly increased their fitness.

3.4 DISCUSSION

We have not attempted a formal meta-analysis of the trials in this review since this would be inappropriate in view of the incompatible data and varying quality of the trials described. This is in accordance with the criteria for attempting a meta-analysis described by Eysenck (1995). The important public health question is whether evidence exists to guide policy makers considering strategies to increase the activity levels of a sedentary population. Trials that were able to demonstrate significant increases in activity involved exercise that was mainly home based, of moderate intensity, involved walking, and had regular follow up.

Walking from home was more successful than exercise which relied on attendance at structured exercise sessions. Only three of seven facility based trials reported increases in exercise compared with six of the twelve home based trials. Six out of eight trials prescribing walking reported increases in activity. Moderate intensity activity was also associated with higher compliance rates. It is possible that in those studies where exercise was self-determined and not prescribed that walking was the preferred mode of exercise.

Although walking is the most prevalent of leisure time physical activities (see chapter 2) walking as a mode of transport has declined by 24% in the last 19 years (DETR, 1999). In addition, only 26% of men and 21% of women walk at a brisk or fast pace, and only 14% of men and 17% of women aged 55-74 walk at this pace (Allied Dunbar National Fitness Survey, 1992). As already mentioned, brisk walking is the focus of strategies for increasing physical activity in many countries (Table 1.1). In England, the Health

Education Authority's Active for Life campaign emphasises the importance of brisk walking for improving one's health.

A United States survey has shown that people in lower income groups, older people, women, blacks and hispanic people, participated in less exercise (Siegel, 1995). These differences were not seen in the numbers who were walking, which indicates that walking may be more universally accessible than other types of physical activity. In England, physical activity participation is lower in older people, women, those living in council properties, lower education groups (Allied Dunbar National Fitness Survey, 1992) and lower socio-economic groups (Cox, 1993).

Walking is also associated with a lower injury rate than other forms of physical activity. (Pollock, 1991). Injuries are reported as a barrier to exercise particularly in older age groups (Allied Dunbar National Fitness Survey, 1992). Reviews of the determinants of physical activity report fewer barriers to walking than other types of physical activity (Hovell, 1992).

Although the studies included here have not specifically compared walking to other modes of exercise, they have provided some evidence that when walking is recommended and attendance at a facility is not required, significant increases in activity can be achieved. Since the first review (Hillsdon et al, 1995) a number of walking studies have been established in England and I eagerly await the results. There is also evidence that when subjects are followed up regularly the increases in walking can be maintained.

In this country the setting of many physical activity interventions has been primary care. 'GP Referral Schemes' or 'Exercise on Prescription Schemes', as they have become known, typically involve referral to a local leisure centre by a GP (General Practitioner) whereupon patients are inducted into a 10-12 week exercise programme at a reduced fee (Fox et al, 1997; Riddoch et al, 1998). Only one of these schemes has been evaluated via a randomised controlled trial (study 19). At eight months follow up there were no significant differences in physical activity between intervention and control groups. Of the 6 studies (8, 11, 12, 16, 18, 19) based in primary care only one showed significant changes in physical activity (18). This trial was unique in that, although the setting was primary care, no primary care staff were directly involved in the intervention. These findings are surprising given that primary care smoking interventions have met with greater success (Thorogood, 1999). This might be explained by the supportive social and physical environment for those wishing to quit smoking after advice from a doctor. Many workplaces are now smoke free, other public places have smoke free areas, smoking is becoming less socially acceptable and is increasingly expensive. None of these factors exist for people trying to increase their physical activity. The social norm is inactivity and there are no financial penalties for being so. An ever more automated society has removed most habitual physical activity from our lifestyles meaning that we now have to make a specific effort to incorporate periods of physical activity into our day.

Most of the studies used volunteers responding to advertisements to take part in a physical activity programme. One study (study 3) that used random digit dialling as a method of recruitment only randomised 27% of those actually contacted, suggesting a high degree of self-selection. (King et al, 1994). However, those who were recruited

through random digit dialling had more CHD risk factors than those recruited via advertisements. A study in Newcastle (study 11) found that opportunistic recruitment from medical centre waiting rooms recruited a greater proportion of those with most to gain from increased physical activity compared to invitations to participate through the post. It is possible that some of the variance in the results of studies reported here could be explained by different recruitment strategies.

Future Research

There is an urgent need for experimental research. In particular:

- there should be more trials undertaken in the UK;
- trials should include groups other than the middle aged, middle class and white;
- there is a need for trials specifically dealing with physical activity in the over 75's;
- there is a need for evaluation of GP prescription schemes by randomised controlled trials;
- there is a need for more evaluation of the effect of GPs advising their patients to exercise;
- there is a need for a broader range of trials, not just those that aimed at the individual.

3. 5 CONCLUSIONS

Levels of physical activity can be increased and the increase can be maintained for at least 2 years. Interventions that encourage walking and do not require attendance at a facility are most likely to lead to sustainable increases in overall physical activity. Regular follow up, which need not be time consuming and expensive, improves the proportion of people able to maintain initial increases.

Brisk walking has the greatest potential for increasing the overall activity levels of a sedentary population and meeting current public health recommendations. It is also the kind of exercise most likely to be adopted by a range of ages, socio-economic and ethnic groups as well as both sexes.

In order to increase the attractiveness of walking for recreational purposes or as a mode of transport, attention will need to be paid to environmental factors which influence personal safety and convenience.

Chapter 4 Theoretical basis of physical activity interventions

4.1 INTRODUCTION

The ultimate success of physical activity interventions in improving peoples' health is dependent upon individuals' willingness to adopt and maintain a physically active lifestyle over many years. The studies reviewed in the previous chapter highlight how difficult this is to achieve. This difficulty is not restricted to physical activity interventions. It has been observed that adherence to professional advice is typically poor when self-directed behaviour change is required (Clark & Becker, 1998). As recently as 1988 it was proposed that little was known about who would exercise, why and for how long (Sonstroem, 1988).

The use of psychological theories of behaviour change along with data on behavioural epidemiology can help our understanding of the predictors of behaviour change and maintenance, guide the development of physical activity interventions and provide a basis for evaluation.

One of the first extensive reviews of the determinants of physical activity, conducted in 1988, noted that few physical activity intervention or adherence studies were based on any theoretical framework. It was suggested that the lack of a theoretical approach may, in part, explain the low level of exercise adherence achieved in these studies (Dishman, 1990). However, a repeat of this review 4 years later found that there had been a distinct improvement in the use of theories in studies and that studies had even started to compare different theories against each other (Dishman & Sallis, 1994).

In addition to progress in the development of psychological theories of behaviour change, interest has grown in the effect of the provider-patient interaction on behavioural, psychological and health outcomes. The communication style adopted by health professionals during consultations has been shown to correlate with patient health outcomes (Stewart et al, 1995).

In this chapter I will describe the most popular theories used in physical activity intervention trials and provide an overview of the so called patient centred method.

4.2 COMMON THEORIES AND MODELS USED IN PHYSICAL ACTIVITY INTERVENTIONS

Of the nineteen trials reported in the previous chapter 11 employed at least one behaviour modification strategy (Table 4.1). These included, stimulus control, reinforcement and self-monitoring. These evolved from the operant conditioning theories of Skinner (1953) who proposed that behaviours such as physical activity can determined by manipulating their antecedents and consequences. Line A in Figure 4.1 represents a simple conceptualisation of the theory.

Antecedents are environmental and physical stimuli that increase the intention to change behaviour. They can be anything from a poster campaign promoting physical activity to receiving advice to exercise following a heart attack. Operant conditioning theory posits that the immediate consequences of a behaviour increase the likelihood of it being performed again. Positive consequences increase the likelihood of the behaviour being performed again while negative consequences reduce the likelihood. Line B in Figure 4.1

Table 4.1 Summary of behaviour modification strategies and theories guiding existing interventions

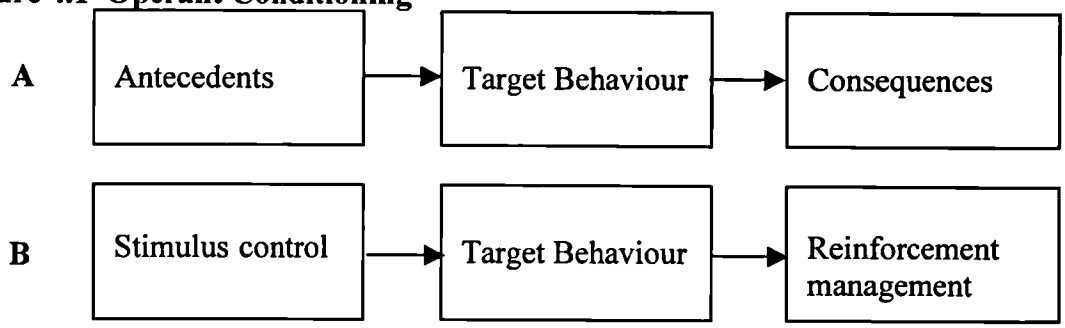
Study	Authors, Year of Publication, Stated Objectives	Behaviour modification	Theory stated	Theory underpinning intervention
1	Kriska, 1986 -To examine factors associated with exercise compliance in post menopausal women	Self monitoring, prompting, social support, reinforcement	No	
2	Lombard, 1995 -To determine the effect of frequency and structure of telephone prompts on frequency of walking	Prompting, goal setting	No	
3	King, 1991 -To determine the effectiveness of group vs. home based training of higher and lower intensities	Self monitoring, prompting, goal setting,	No	Social cognitive theory
4	Noland, 1989 - To assess effects of behavioural techniques on adherence to unsupervised exercise	Self monitoring, reinforcement	No	
5 & 6	King, 1988 - To evaluate strategies for enhancing the maintenance of exercise training by healthy middle aged men and women (also see number 6)	Self monitoring, prompting	No	
7	Godin, 1987 - To investigate the effectiveness of fitness testing and health appraisal on exercise intention and behaviour		Yes	Theory of reasoned action
8	Bull, 1998 - To test the effectiveness of verbal advice on exercise from a family physician, plus written materials, in a primary health care setting			
9	Chen, 1998 - To evaluate a minimal behavioural intervention program designed to promote walking among initially sedentary ethnic minority women	Social support	Yes	Social cognitive theory Relapse prevention
10	Marcus, 1998 – To compare the effectiveness of a motivationally tailored and standard self help materials for physical activity adoption		Yes	Stages of change
11	Harland, 1999 - To evaluate the effectiveness of combinations of three methods to promote physical activity	Reinforcement	Yes	Stages of change/ motivational interviewing

Table 4.1 continued

Study	Authors, Year of Publication, Stated Objectives	Behaviour modification	Theory stated	Theory underpinning intervention
12	Goldstein, 1999 - To test the efficacy of a brief physician counselling session compared to usual care on self reported physical activity		Yes	Stages of change and social learning theory
13	McAuley, 1994 - To determine the utility of an efficacy based intervention on exercise participation		Yes	Self efficacy
14	King, 1984 - To study the effect of two low cost methods of increasing the number of participant controlled jogging episodes	Social support	Yes	Relapse prevention training
15	MacKeen, 1985 - To study the effects of an 18 month exercise intervention on adherence.		No	
16	Reid, 1979 - To assess the effectiveness of physician prescribed exercise programme with health education and self monitoring components.	Self monitoring,	No	
17	Marcus, 1993 - To assess effectiveness of a relapse prevention programme and reinforcement programme in increasing exercise adherence and short term maintenance	Reinforcement	Yes	Relapse prevention training
18	Stevens, 1998 - To assess the cost effectiveness of a primary care based intervention aimed at increasing physical activity in inactive people aged 45-74			
19	Taylor, 1998- To examine the effects of a GP exercise referral scheme on modifying physical activity and other CHD risk factors	Goal setting		

shows the intervention techniques used to manipulate the antecedents and consequences of the target behaviour.

Figure 4.1 Operant Conditioning



Stimulus control

Stimulus control is the process of manipulating the antecedents of a behaviour, such as physical activity, by increasing the cues and prompts for it and reducing them for physical inactivity. The intention is to prompt the initiation of the target behaviour. A common example is the positioning of sweets and chocolates at checkouts in supermarkets where adults and children are forced to wait temporarily. The classic example of this in an exercise setting is the use of a poster promoting the benefits of using the stairs at the bottom of a busy escalator in a train station. During the weeks the poster was there stair use increased. When the poster was removed stair use reduced (Brownell et al, 1980; Blamey et al, 1995). Unfortunately, in today's automated society the environment is flooded with cues for being sedentary.

The most common application of this principle, in the trials summarised in tables 3.2a and 3.2b, was telephone reminders. Calls were normally made every few weeks or so and lasted just a few minutes. The frequency rather than the content of calls is associated with better exercise adherence (Lombard et al, 1995).

Reinforcement

If the immediate consequences of a behaviour lead to an increased probability that the behaviour will be performed again they are regarded as reinforcing. Reinforcement can both positive and negative. Positive reinforcement is when the person finds the consequences of a behaviour rewarding. For exercise this might include feeling refreshed, having more energy, or receiving praise and encouragement from others. Negative reinforcement also leads to an increase in behaviour but does so by reducing or eliminating a negative state or aversive stimuli. For example many people use exercise to reduce stress or feelings of lethargy. Negative reinforcement should not be confused with punishment which uses negative consequences to reduce the frequency of a particular behaviour. Common punishments associated with physical activity that may reduce its frequency are boredom and muscle soreness.

Reinforcement management involves attempts to manipulate the consequences of the target behaviour to increase the probability that they are reinforcing. In the physical activity trials reviewed in the previous chapter, reinforcement management mainly involved external rewards such as free lottery tickets, badges, T-shirts, reviews of progress and praise from practitioners. Reinforcement can also be internal in terms of feeling a sense of mastery for successfully completing the behaviour, enjoying the exercise process itself and generally feeling good about one-self. It has been suggested that internal reinforcement might have a longer lasting effect than external reinforcement (Deci & Ryan 1987).

The antecedents and consequences of physical activity that promote change will vary for each individual. Part of the self-management of physical activity is learning what these are for one-self. To achieve this, many studies ask subjects to *self-monitor* their physical activity. This normally involves keeping a logbook or diary of physical activity each day for a specified time period, often a week. The idea is that individuals establish their own system of cues, prompts and reinforcers. One study (King et al, 1988) found that the frequency of self-monitoring was associated with a higher frequency of physical activity. Another (Reid & Morgan, 1979) found that self-monitoring was only completed by those successfully adhering to the physical activity programme.

The review of physical activity determinants and interventions by Dishman and Sallis (1994), found that the use of at least one behaviour change method was better than none at all. They were unable to determine whether one was better than another because they were often part of multi-factor interventions. King et al (1992) found that behaviour modification techniques, such as these described above, lead to increases in the frequency of physical activity of 10-75% compared to no treatment control groups.

Subjects in 2 studies reviewed in the previous chapter (studies 9 and 14, Table 3.2) educated subjects about the importance of social support and encouraged them to actively seek it from friends, neighbours and family. Support from these sources can involve encouragement and praise or more direct support such as exercising together. This kind of support has been shown to be associated with changes in physical activity over 2 years (Sallis et al, 1992). As well as acting as prompts for physical activity, telephone calls from health/fitness professionals can also be a means of providing support.

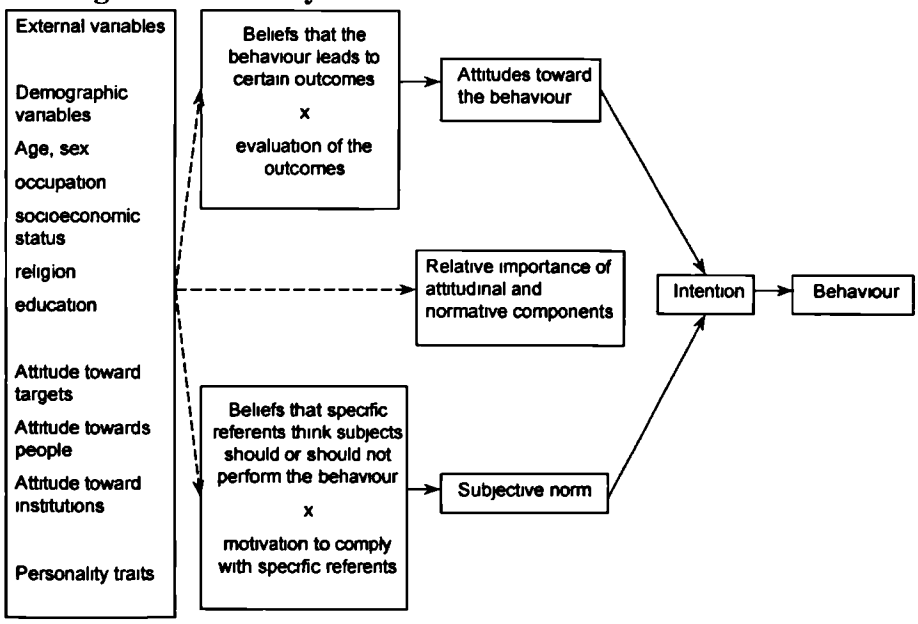
Four theories were cited by 9 of the studies reviewed in chapter 3 as guiding the intervention (Table 4.1). They are listed below.

- Theory of reasoned action
- Stages of change
- Social cognitive theory
- Relapse prevention

Theory of reasoned action

The Theory of Reasoned Action (Fishbein & Ajzen, 1975) posits that the most important determinant of behaviour is a persons behavioural intention and that intention is determined by the persons attitude towards the behaviour plus the influence of social factors. The theory is presented diagrammatically in Figure 4.2.

Figure 4.2. Theory of Reasoned Action



Attitude is a function of personal beliefs about the perceived consequences of engaging in a behaviour and an evaluation of those consequences. If the person believed that taking part in regular physical activity would lead to valuable consequences they would be expected to have a positive attitude towards physical activity. Subjective norm is a function of the views of important others in the person's life regarding the target behaviour, weighted by how motivated the person is to act on their views.

If a person predicts that only valued positive outcomes will arise from increased physical activity and important others, whose views are respected, approve of increased physical activity, then the theory would predict high physical activity intentions.

A third construct, perceived control, was added to the model to account for those elements of physical activity that are not under volitional control (Ajzen, 1985). Ajzen argued that the greater the control a person perceives they have over a behaviour the more effort they will put into performing it.

A review of physical activity studies of intention found that the mean correlation between intention to exercise and exercise behaviour was 0.55, explaining 30% of the variability in exercise (Godin, 1994).

Transtheoretical/Stages of Change Model

In the last decade the Transtheoretical or stages of change model has received most attention (Prochaska, et al, 1992; Marcus & Simkin, 1994). It is grounded in social cognitive principles. The model was developed to help understand more about the determinants of smoking. One of the major themes of this model is that behaviour change

involves movement through a series of stages before change is achieved. These stages appear to exist for both self-changers and those attending a treatment programme. The entry point to the change process is the *precontemplation* stage. At this point the subject is not considering the possibility of change at all. The next stage is *contemplation,* when subjects start to consider the need for change. This stage is characterised by ambivalence where the subject simultaneously thinks about reasons for change and the amount of effort, energy and loss that may be required to achieve change. After considering all of the pros and cons of change, subjects will make a commitment to change and move to the *preparation* stage. Subjects at this stage are seriously intending to change their behaviour in the very near future and are seeking a change strategy that is acceptable, accessible, appropriate and effective. When individuals begin to modify their behaviour they are said to be in the *action* stage. The action stage continues for up to six months after which subjects move into the *maintenance* stage. During this stage subjects have successfully modified their behaviour for a period of time and are working to prevent relapse. Relapse is the rule rather than the exception in behaviour change and most people will travel around the stages of change a number of times before achieving permanent change.

One of the most important lessons to be learnt from research into this model is that different processes or strategies are required at the different stages. This has important implications for practitioners working one to one with subjects. The model argues that practitioners should adopt different approaches depending upon where the subject is in the stages of change, which reflects a subject's *readiness* to change. Most practitioner interventions are action orientated. Advice about what action to take to achieve change is misdirected and premature as most subjects are not in the action stage. Instructing subjects about the need for change who are in precontemplation, contemplation or

preparation is likely to be counterproductive and result in defensiveness and resistance (Rollnick et al, 1992).

A before and after study examining the use of the stages of change model in an exercise intervention provided preliminary support for the use of this model in the design of exercise interventions (Marcus et al, 1992). However, the one randomised controlled trial found, which has compared a stage matched intervention to a standard, non-stage matched intervention for increasing physical activity was unable to show any between group differences, although both groups increased over baseline (Marcus et al, 1999).

Social Cognitive Theory

Social cognitive theory (Bandura, 1986) developed from Social Learning Theory (Bandura, 1977) and posits that behavioural, personal and environmental factors are reciprocal, interacting determinants of each other. The theory refers to this as reciprocal determinism, meaning that behaviour is not simply the result of the environment and the person, just as the environment is not simply the result of the person and the behaviour. Instead, the three components are constantly interacting. A change in one has implications for the other. Two kinds of expectations are central to social cognitive theory: outcome expectations and efficacy expectations. Outcome expectations are beliefs about whether a given behaviour is likely to lead to certain outcomes and is similar to the attitude construct in the Theory of Reasoned Action. Self-efficacy refers to a persons perception of how capable they are of performing the behaviour that will lead to given outcomes. Self-efficacy is often evaluated independently of the theory's other constructs and is influenced by a) previous experience of the behaviour; b) vicarious experience, which means learning the behaviour by observing it being performed by someone similar to the

observer; c) verbal persuasion in the form of encouragement from others and d) physiological arousal, which refers to the extent to which we interpret sweating, increased respiration and heart rate as signs of vulnerability (Clark & Becker, 1998).

Self-efficacy has been shown to be predictive of physical activity participation (Garcia & King, 1991) and manipulating the components of self-efficacy can lead to changes in physical activity (McAuley et al, 1994).

Study 3 in Table 3.2a is probably the most comprehensive application of the theory. It used a whole range of strategies based on the various principles of the theory. They are summarised in Table 4.2. At 2 years intervention subjects were performing significantly more physical activity than controls (King et al, 1991).

Table 4.2 Elements of a programme based on Social Cognitive Theory

Programme design
Written description of the benefits of exercise
Assessment of exercise expectations
Review of expectations to make them realistic
Assessment of self-efficacy and skills training to enhance it
Videotape instruction on exercising safely
Identification of enjoyable exercise settings
Self-monitoring through diaries and hear rate monitors
Reinforcement through staff phone calls, fitness evaluations and T-shirts
Development of a plan to cope with interruptions to exercise

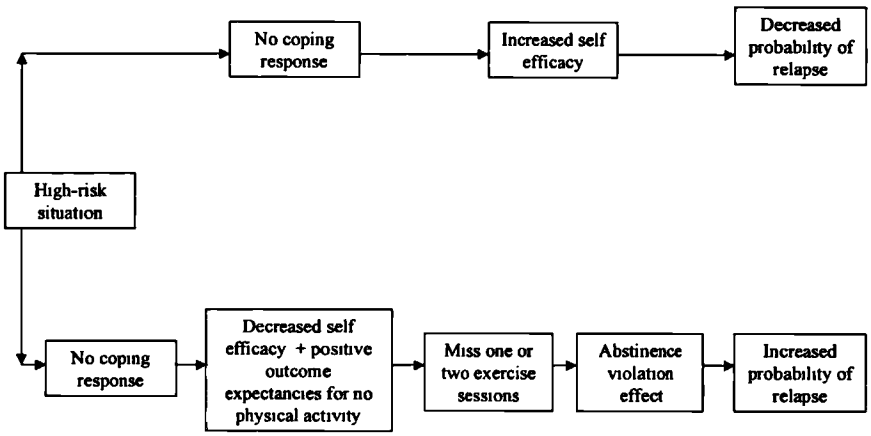
Adapted from Barr Taylor (1998).

Relapse Prevention

Maintaining a programme of regular physical activity is a major challenge for people, with estimates that 50% will relapse from a supervised programme in the first 6-12 months (Dishman, 1982). Relapse prevention strategies combine cognitive and behavioural procedures to help people cope with obstacles and barriers to maintaining

newly adopted behaviours and thus prevent them from returning to their old behaviour (Marlatt & Gordon, 1985). The model was first developed for studying abstinence from alcohol but has since been applied to other health behaviours including physical activity. A model of the relapse process is presented in Figure 4.3.

Figure 4.3. The Relapse Prevention Process



Adapted from Marlatt & Gordon, 1985.

Both possible scenarios shown in Figure 4.3. start with a high risk situation such as social pressure not to exercise, depression, boredom or competing time demands. If the person hasn't prepared a strategy for dealing with the situations their self-efficacy for exercise reduces and they start to focus on the benefits of no exercise. This leads to an initial slip or lapse in the frequency of exercise. The abstinence violation effect (abstinence comes from alcohol studies) refers to beliefs the person holds about the importance of slipping back from their plan to be more active and typically involves all or nothing thinking e.g., "Because I've slipped that means I'm off the programme completely." These kind of beliefs often lead to the person attributing their failure to a lack of control and an

indication of their inability to change. This sequence of events increases the probability of a return to the old behaviour. When a person has thought in advance about possible high risk situations, and planned for them, their self-efficacy for continued exercise increases and the risk of relapse is reduced.

A randomised controlled trial of relapse prevention training and social support in young women found that at 3 months those receiving relapse prevention training alone were jogging more than those receiving only social support, social support and relapse prevention training or no intervention (King et al, 1984). A larger study with more intensive relapse prevention training did not find any significant differences in physical activity between the relapse group, a reinforcement group or controls at a 2 month post intervention follow (Marcus & Stanton, 1993).

Summary

Although these models go some way in helping us understand physical activity behaviour, and have influenced interventions, no one model can explain a high percentage of the variance in physical activity. This might be expected as the models focus on psychological factors and generally ignore environmental ones (Marcus et al, 1996). More research is required to help us understand this complex behaviour. In particular, we need to understand more about ecological models. They refer to the interaction between people and their social and physical environments (Stokols et al, 1996). In practice this means that environmental and policy variables would be expected to add to the explanatory power of just intrapersonal and interpersonal variables. It has been argued that such variables hold the most promise in understanding physical activity (Sallis & Owen, 1999).

4.3. A PATIENT CENTRED METHOD

Patients are often dissatisfied with many aspects of their consultations with health professionals and dissatisfaction has been shown to be correlated with low compliance with medical regimens (Ley, 1988). In fact it has been estimated that only approximately 50% of patients will adhere to long term drug regimens and perhaps even less adhere to advice to alter their lifestyle (Becker, 1985). Concern about the emerging evidence relating to low rates of patient satisfaction led to researchers, in the 1970s, beginning work on a new model of medicine and medical training called "Patient-Centred Medicine." Patient-Centred Medicine was first introduced in 1970 by Balint et al (1970) and has since been developed into a "patient centred model" model by Levenstein (1984) and then perhaps most extensively by Stewart et al (1995).

Stewart et al (1995) describe six interconnecting components of the patient-centred model.

Exploring both the disease and the illness experience

This involves assessing the disease using conventional medical methods. In addition, it involves assessing the patients' illness experience in terms of what they believe is wrong with them, their feelings about being ill, what effect their illness has on their normal life and their expectations about what should be done.

Understanding the whole person

This component refers to understanding the disease and the person's experience of illness in the context of their family, the stage of life they are in and any cultural or religious beliefs that they may hold.

Finding Common Ground

This involves both practitioner and patient working together to define the problem, developing a suitable management plan and to understand each other's expectations.

Incorporating prevention and health promotion

The fourth component emphasises the need to incorporate prevention and health promotion into each routine consultation. Practitioners and patients monitor aspects of the patient's life that might influence long term emotional and physical health.

Enhancing the patient-doctor relationship

Practitioners should work on developing an effective long term relationship with patients and to use the relationship for its healing potential. This involves understanding that different patients respond to different approaches and being sensitive to this.

Being realistic

The final component of the model involves practitioners being realistic about what can be achieved in time pressured consultations and also in terms of their own energy.

The patient centred method has been shown to be associated with compliance with pill taking, patient satisfaction and a reduction in concerns about symptoms (Stewart, 1984; Stewart et al, 1995; Henbest & Stewart, 1990). Research into the effect of the patient centred method and health outcomes is limited and has met with mixed results (Meland et al, 1997; Pill et al, 1998; Butler et al, 1999). One important weakness of the studies to date has been their failure to measure the clinician's patient centredness (Coleman, 1999).

One study that did measure clinician's adherence to the method found that only 19% of them were applying it systematically after 2 years (Pill et al, 1998).

Most of the development and research into this approach has focused on clinical encounters with patients presenting with symptoms. However, a similar framework for achieving health behaviour change has been proposed by Rollnick et al (1999). This adapted application of the patient centred method is based on the principles of motivational interviewing with a particular focus on the ambivalence people experience when they are considering behaviour change (Miller & Rollnick, 1991; see chapter 6 for details). Consistent with the Transtheoretical Model (Prochaska et al, 1992), Rollnick and colleagues posit that patients vary in how ready they are to change their behaviour and practitioners actions need to be in harmony with each patient's readiness to change or risk patient resistance. The amount of resistance in a consultation has been shown to be predictive of behavioural outcomes and is mainly determined by the practitioner's style of working (Miller et al, 1993).

The patient centred method has been proposed as a key element in a practical model of counselling on health related physical activity (Laitakari, 1998), although the method has not been tested empirically in studies of physical activity.

The importance of the relationship between health professionals and patients has been recognised by the government. In a soon to be released policy document entitled Patient and Public Involvement in the New NHS, it states that one strategy will be to "promote patients' participation in their own care as active partners with professionals" (Stuart, 1999).

Summary

There appears little doubt that in some way or other practitioner behaviour affects a number of different patient outcomes. What is less clear is exactly what practitioner behaviour leads to the best outcomes. Research is also required to look at the best ways of applying the different theoretical models in time limited consultations and to look at longer term health outcomes. In particular, research is required address whether it is possible to get clinicians to change their consulting room behaviour.

Chapter 5 Methodology

5.1 INTRODUCTION

The focuses of this chapter are the measurement of physical activity and choice of study design. Accurate measurement of physical activity is essential as we attempt to understand its determinants. Unfortunately, at present there are no widely accepted methods for measuring physical activity. Usual practice has been either to design ones own method or to adapt an existing one that may have been developed on a different population from the one being studied. This chapter will review the methods used in the trials identified in chapter 3 and address in general some of the methodological problems associated with measuring physical activity.

Methods of evaluating health promotion have been the focus of many debates in the public health literature in recent years. The randomised controlled trial is seen by some as the gold standard of evaluation and by others as unethical. The strengths and weaknesses of this approach will be considered here.

5.2 DEFINITION OF PHYSICAL ACTIVITY

It is important to clarify what is meant by the term physical activity before describing ways of measuring it. The use of terms such as physical activity, exercise and energy expenditure are often used interchangeably when in fact they can mean very different things. In this thesis the definition of physical activity proposed by Caspersen et al., (1985) will be used.

"Physical activity is any bodily movement produced by contraction of skeletal muscles resulting in caloric expenditure."

Caspersen distinguished between physical activity and exercise by defining exercise as a sub-category of physical activity that is planned, structured and repetitive. The definition of physical activity used by Caspersen means that it can be measured along multiple dimensions making assessment of any individuals activity, even over the course of a day, a complex issue. For convenience, total physical activity is commonly subdivided into three broad headings:

- Occupational physical activity
- Leisure time physical activity
- Activities of daily living

As mentioned in chapter 1 each of these types of physical activity can then be measured in terms of frequency, duration and intensity.

5.3. MEASURING PHYSICAL ACTIVITY

Measures of physical activity should be distinguished from measures of physical fitness, energy expenditure, or bodily movement. The last three are objective measures which measure correlates of physical activity and are sometimes used to validate self-reported measures of physical activity. Intervention studies aim to produce modifications in physical activity behaviour and therefore an accurate and reliable measure of physical activity is required. Physical activity is a behaviour and as a result measurement is nearly always dependent on self-report. Occasionally, 'significant' others such as relatives, partners or colleagues are used to observe the person under observation (Chen et al, 1998), but on the whole the person under observation is asked to record various components of their physical activity for a specified period of time by one of a number of different methods.

As mentioned in section 5.2 total physical activity is usually the sum of occupational physical activity, leisure time physical activity (including competitive and non-competitive sports) and activities of daily living (including housework). A wide variety of questionnaires exist for measuring physical activity, most of which were developed for prospective, cohort studies examining the relationship between physical activity and health outcomes. The category of physical activity most frequently measured in early studies was occupational physical activity. This usually amounted to no more than coding job classifications. The measurement of this category of physical activity is less appropriate in intervention studies as it is less conducive to change compared to leisure time physical activity and activities of daily living.

Any self-reported physical activity risks recall error, subjects failing to accurately recall the activities they have done. For this reason it has been common for questionnaires to focus on leisure time activities that are structured, organised and more vigorous activities. These activities usually take place at specific times, for set periods of time and require a reasonable degree of effort to participate. Each of these factors make them easier to recall and therefore less prone to recall error. In addition, these type of activities correlate better with the objective measures of fitness compared to more habitual activities (Knapik et al, 1993). However, these types of activities only make up a very small amount of most people's total, daily physical activity (Allied Dunbar National Fitness Survey, 1992). Also, most observational studies of physical activity and CHD mainly included men and therefore physical activity measures have reflected those types of physical activity most likely performed by men. As there are significant differences in the activity patterns of men and women (Allied Dunbar National Fitness Survey, 1992), questionnaires designed

predominantly for men may not accurately capture the physical activity being undertaken by women.

Any questionnaire should measure the types of physical activity that contribute the greatest proportion of total physical activity in the study population. Choosing a measurement device depends on the types of physical activity under study, the size and demographics of the study population, the acceptability of the measure to the study population, the cost of producing the measure, time to administer, time to process, reliability and validity of the measure and the degree to which the measure might interfere with usual physical activity (Montoye et al, 1996).

Common techniques used for gathering self-reported physical activity in intervention studies include:

- Diaries
- Logs
- Recall Surveys
- Retrospective quantitative histories

Diaries

Physical activity diaries require subjects to record all physical activity performed each day for a set number of days. Subjects are usually expected to record the nature of the activity performed, the duration of that activity and possibly some subjective rating of effort. The typical time frame is between 2 and 7 days. They are cheap to administer as many subjects can be completing them at the same time without the need for an observer or administrator. As each physical activity is recorded close to the actual time of performance, recall error is minimised. Processing diary data is time consuming as data has been recorded in open text fields and requires coding in some way. If the energy cost

of physical activity is to be estimated this makes the processing even more time consuming and expensive. Open text diaries require extensive effort and persistence from the subject, hence the relatively short periods of data collection. This may lead to errors in recording due to tedium or forgetfulness if diaries are completed at the end of the day. Another consequence of the effort required to complete diaries may be the effect on actual behaviour during the observation period. Whilst completing diaries, subjects may reflect on their behaviour and decide to change it. Also, knowing that their diaries will be observed by researchers may lead to a change in behaviour or favourable reporting, the so called Hawthorn effect (Brown, 1954). The short observation period makes validating diaries by objective measures easier than methods using longer recall periods.

Diaries have been shown to be a reasonably accurate measure of daily energy expenditure (Montoye et al, 1996, Acheson et al. 1980).

Logs

Log books are very similar to diaries in that subjects complete them either as each activity is performed or at the end of a day. The main difference is that they list specific activities like a checklist rather than an open text form. Subjects record each time they have performed an activity from the list, the duration of the activity and possibly a subjective indication of effort.

The use of predetermined activity lists makes data processing simpler than open text and is therefore quicker and cheaper depending on how many days of activity have been recorded. However, to be confident that the log captures the subjects usual physical activity habits, the lists used need to reflect common activities performed by the particular

population under study and should not be limited to organised, structured activities that make up so little of most peoples overall physical activity.

The short observation period usually used in diaries and logs may be less likely to reflect 'usual' physical activity compared to recall surveys which can focus on time periods up to a year. Other advantages and disadvantages of logs are the same as those for diaries.

Recall surveys

Physical activity questionnaires require individuals to recall participation in various physical activities for time periods of 1 week to up to 1 year with some assessing usual physical activity. These type of questionnaires are more prone to recall error than diaries (Baranowski, 1985) but are simpler to complete and are therefore less likely to interfere with actual behaviour.

Recall surveys are the usual method for assessing population levels of physical activity as part of national surveys such as the Allied Dunbar National Fitness Survey and the Health Survey for England (Allied Dunbar National Fitness Survey; 1992, Joint Health Surveys Unit, 1996). Both of these surveys used a 4 week recall period although sport and active recreation were also assessed in the National Fitness Survey for the previous year. The 4 week recall period was used after development work had shown that this period was the longest that people could provide accurate information about current physical activity for. This period was also expected to provide a stable estimate of usual physical activity minimising the risk of misclassification.

Recall surveys usually enquire about the frequency and duration of different types of physical activity. Estimates of intensity of physical activity are normally limited to global

questions such as "How often did you perspire during physical activity in the last week?" (Caspersen et al, 1991).

Early physical activity questionnaires designed for prospective cohort studies, limited their enquiries to occupational physical activity (Morris et al, 1953). As it became clear that occupational physical activity was reducing in industrialised countries, leisure time physical activity became the focus of attention. Men were usually the attention of these studies and therefore questionnaire items emphasised more strenuous activities such as sport and recreation, although many included items on walking (Anderson et al, 1978). Although recall of strenuous activities may be more accurate than moderate or mild activities (Taylor et al, 1984), these type of activities are more frequently performed by men and younger adults and therefore are likely to underestimate activity levels of women and older adults.

More recent recall surveys have been more comprehensive including items on home activities, walking, gardening, DIY, occupation as well as sport and recreation (Allied Dunbar National Fitness Survey, 1992). This amount of detail increases the time of completion and processing and therefore its cost.

Recall surveys have been shown to correlate with cardiorespiratory fitness, body fat and motion detection (Ainsworth et al, 1993).

Retrospective quantitative histories

The retrospective quantitative history enquires about month by month frequency and duration of a long list of different activities (Taylor et al, 1978). The time frame is

typically 1 year and therefore the risk of recall error is high. However, this is the most comprehensive of recall surveys and can provide a good representation of year round activity. Data covering up to 1 year can accommodate seasonal variations in physical activity and other variations due to sickness or holidays.

The time of administration and processing make this an expensive alternative.

5.4 SUMMARISING QUESTIONNAIRE DATA

Existing intervention studies interpret questionnaire data in terms of energy expenditure, meeting predefined levels of physical activity, occasions of activity performed from broadly defined categories such as vigorous, moderate and light, or the number of exercise sessions attended.

As all physical activity leads to energy expenditure it is common to interpret questionnaire data in terms of this. Total daily energy expenditure (TDEE) is the sum of resting metabolic rate (the energy cost of sustaining vital organs and balance in the resting state), the thermic effect of food (the energy cost of metabolism) and physical activity. Resting metabolic rate (RMR) accounts for approximately 60-75% of TDEE, with the thermic effect of food accounting for approximately 10% and physical activity 15-30%. Physical activity has the greatest capacity for effecting TDEE (McArdle et al, 1996).

Accurately estimating TDEE is difficult although some physical activity questionnaires have expressed their data in this way (Blair, 1984). It is more common to report the total energy expenditure of the physical activities recalled by the assessment instrument. This is done by assigning an energy cost to each activity from published tables (Ainsworth et al, 1993) multiplying this by the duration of the activity and then by the frequency of the

activity. The energy cost assigned to each activity is an absolute estimate of energy expenditure with units being either kilocalories per minute or METs (see chapter 1, section 1.2). Energy expenditure can be expressed as MET-hours per week or kilocalories per kilogram bodyweight per week (1 MET is approximately equivalent to 1 kilocalorie per kilogram bodyweight per hour). Two main limitations exist when assigning energy costs from published tables to individual physical activities. One is the assumption that the energy cost for a given activity is the same across subjects. Depending on skill level, initial fitness and pace or level of participation, the energy cost of a given activity can vary considerably across subjects. Secondly multiplying the frequency and duration of a physical activity by a MET value assumes that bodyweight is proportional to resting metabolic rate and that the relative increase in metabolic cost of a given activity is constant across subjects irrespective of bodyweight (Kriska & Caspersen, 1997).

As national and international recommendations now exist for physical activity and health, some interventions studies report the proportion of subjects meeting these recommendations. However, in order to do this physical activity data still has to be scored in terms of frequency, duration and intensity. The recommendations represent practical, behavioural interpretations of epidemiological data which was originally reported in terms of energy expenditure. This threshold approach to interpretation may hide significant changes in physical activity by some subjects, particularly those who were very sedentary at the outset of the study. A person could be performing the equivalent of a 1,000 kilocalories of leisure time physical activity per week without meeting either the 3 times per week of 20 minute occasions of vigorous activity or 5 times per week of 30 minute occasions of moderate activity recommendations.

Reporting occasions of moderate and vigorous intensity physical activity and using these to rank subjects level of physical activity suffers from similar difficulties as those described above. Firstly, it is necessary to define an occasion. This is arguably an arbitrary definition as the exact dose of physical activity required to derive health benefits is not known. If 'active' is defined as five, 30 minute occasions of moderate intensity physical activity per week then a subject who performs six, 25 minute moderate intensity occasions would not be classified as active.

Intervention studies which only report attendance at organised exercise classes may underestimate the effect of the intervention. As a result of the intervention, subjects may make changes in other areas of physical activity other than those provided by the intervention. They may fail to attend many classes at all and be classified as having not changed, yet might actually by walking an extra 5 miles per week.

Physical activity measures used in intervention studies need to be sensitive enough to detect relatively small changes in physical activity. Subjects may for example, on average, increase their physical activity by two 1 mile walks per week. If thresholds of activity are used to measure change then they may be misclassified. Therefore, the greatest flexibility in interpreting results can be achieved by summarising physical activity in terms of energy expenditure summed from the total of all physical activities performed during the recall period. Davey-Smith and Morris (1992) have proposed that data collected is more reliable if check lists of common activities are used which allow for people to make there own additions. They prefer this approach to the recall of broad categories of physical activity such as moderate and vigorous. Similar observations have been made about the measurment of alcohol consumption (Dawson, 1998).

5.5 EXISTING METHODS OF MEASURING PHYSICAL ACTIVITY

Table 5.1 summarises the methods of measuring physical activity in the trials identified in Chapter 3. The main measure of physical activity in all 19 studies was a subjective measure using either a self or interviewer administered recall survey. The time frame of the surveys varied from 7 days to 12 months, although 1 - 4 weeks were the most common referent period. Nine of the studies used questionnaires developed by others with published validity and reliability data. However, of the nine studies, five did not use the questionnaires as originally designed which brings into question their validity and reliability. Only one study had published data on validity and reliability for the study population (study 9). Some studies used objective measures such as fitness tests and motion sensors to validate their questionnaires. This will be described in more detail in section 5.6.

Most survey methods focused on leisure time physical activity and activities of daily living. This seems appropriate as they were being used in intervention studies rather than observational studies. Occupational activity is not conducive to change and is therefore not normally the focus of interventions.

No two studies used the same survey method in terms of measure used and the mode of administration. This highlights the lack of agreement about how best to assess this complex behaviour and makes comparisons between interventions virtually impossible.

Table 5.1 Methods of assessing physical activity in existing trials

Study Number	Measure of physical activity	Time frame of measure	Mode of administration used	Published validity and reliability data	Measure used as originally described	Validity and reliability reported for study population
1	Paffenbarger Physical Activity Questionnaire	Past week	Not stated	Yes	Yes	No
2	Lipid Research Clinics Questionnaire	Usual physical activity	Self completion	Yes	No	No
3	Activity logs	Recorded daily returned monthly	Self completion	No	N/A	No
4	Activity logs and self completion questionnaire	2 weeks for activity logs. Not specified for questionnaire	Self completion	No	N A	No
5 & 6	Activity logs	Recorded daily returned monthly	Self completion	No	N/A	No
7	Godin Leisure-Time Exercise Questionnaire	Usual activity	Self completion	Yes	Yes	No
8	National Heart Foundation of Australia Risk Factor Prevalence Survey	Previous 2 weeks	Self completion	Yes	Yes	No
9	National Health Interview Survey	Previous 2 weeks	Interviewer administered	Yes	Yes	Yes
10	Seven-Day Physical Activity Recall	Previous 7 days	Self completion	Yes	No	No

Table 5.1 continued

Study Number	Measure of physical activity	Time frame of measure	Mode of administration used	Published validity and reliability data	Measure used as originally described	Validity and reliability reported for study population
11	National Fitness Survey Questionnaire	Previous 4 weeks	Interviewer administered	No	No	No
12	Physical Activity Scale for the Elderly	Previous 7 days	Interviewer administered	Yes	Yes	No
13	Activity logs	Daily	Self completion	No	N/A	No
14	Questionnaire	Previous 2 months	Self completion	No	N/A	No
15	Minnesota Leisure Time Physical Activity Questionnaire	Previous 12 months	Interviewer administered	Yes	Yes	No
16	Questionnaire	Previous month	Not stated	No	N/A	No
17	Questionnaire	Previous 2 months	Self completion	No	N/A	No
18	National Fitness Survey Questionnaire	Previous 4 weeks	Self completion	No	No	No
19	Seven-Day Physical Activity Recall	Previous 7 days	Self completion	Yes	No	No

5.6 VALIDITY AND RELIABILITY

Whatever measure of physical activity is used it should have been assessed for reliability and validity. Reliability refers to how consistently a questionnaire can provide the same results when repeated over a period of time (Kriska & Caspersen, 1997). It is slightly problematic in test-retest measures of physical activity as the measurement device itself may produce some change in behaviour making low correlations difficult to interpret.

Validity assessments of physical activity questionnaires usually refer to concurrent validity, that is the extent to which the instrument measures what it intends to measure (Bowling, 1997). This requires a gold standard instrument against which a questionnaire can be compared. This is a major obstacle to validating physical activity questionnaires as no gold standard measure of physical activity exists (Montoye et al, 1996). As a result researchers have used a variety of objective measures to validate questionnaires (Wareham & Rennie, 1998). This has included assessing correlations between different questionnaires and diaries. This is always problematic as each subjective measure of physical activity will have its own correlated error making it difficult to determine whether the questionnaire being assessed or the comparison method is valid. Other measures such as motion sensors, fitness tests and heart rate monitors have all been used to validate questionnaires. However, as they all have different units of outcome measure they cannot readily be used to validate questionnaires (Montoye et al, 1996).

If questionnaires are interpreted in terms of total energy expenditure then they can be compared to the doubly labelled water method for measuring energy expenditure. This technique is accepted as the gold standard for estimating TDEE questionnaires (Wareham & Rennie, 1998). The major barrier to its widespread use is the cost.

Perhaps what can best be expected is corroboration of self-reported physical activity by some objective measure that is relatively cheap and non-invasive via measurement of agreement (Bland & Altman, 1986). In other words, one would expect to see high levels of agreement between a subjective measure of physical activity and an objective one if the subject was in fact performing the activities that they reported. Fitness tests remain problematic for this as the types of physical activity that might result in increases in physical fitness may not be the focus of the intervention. Also, there is a large hereditary component to physical fitness (Bouchard, 1998). Most potential probably exists for heart rate monitors and motion sensors. Individually calibrated heart rate monitors have been shown to be an accurate measure of individual energy expenditure when compared to doubly labelled water methods (Livingstone et al, 1990). The TriTrac-R3D accelerometer (Hemokinetics, Madison, WI) is a commercially available device which can detect body acceleration in three planes and produces an output in kilocalories per minute. When compared to indirect calorimetry it does not estimate energy expenditure for different activities particularly well. Despite this, these devices have been shown to be highly correlated with energy expenditure measured using indirect calorimetry and are regarded as a reasonable means of differentiating between individuals active at different levels (Jakicic et al, 1999).

5.7 STUDY DESIGN

Research that attempts to answer questions relating to the effectiveness of one intervention over another are best answered by a randomised controlled trial (Sackett & Wennberg, 1997). Randomised controlled trials (RCTs) randomly allocate subjects to intervention and control groups to increase the probability that the only difference between subject groups is their exposure to the intervention (Hennekens, 1987). The process of randomisation increases the probability that a study has internal validity. That is, any observed differences between intervention and control groups in the outcome of interest can be attributed to the intervention rather than any other confounding factors (Bowling, 1997). Confounding factors influence both the intervention and outcomes and often include factors such as age and social class. In randomised controlled trials known and unknown confounding factors can be assumed to be evenly distributed between intervention groups. The unit of randomisation is usually the individual subject although sometimes groups of people are randomised. When groups are randomised this is known as cluster randomisation (Jadad, 1998). Examples include families, households and hospitals.

Control groups can be usual or standard treatment, placebo or no intervention groups. Usual treatment is favoured when a standard treatment has already demonstrated its effectiveness compared to doing nothing. Placebo control groups are common in drug trials where the treatment drug and a placebo drug are identical apart from the active ingredient. Placebo controls groups attempt to control for the effect of patients reporting they 'feel better' because they believe they have been taking an effective treatment. No intervention control group subjects receive no intervention at all and using such a comparison group has the advantage of being able to estimate the extent to which any

observed changes in the intervention group are as a result of secular trends in the population.

It is a well known phenomena that subjects being observed in trials may behave differently simply as a result of the extra attention they are receiving. This is known as the Hawthorn effect (Brown, 1954) and may produce better outcomes than would normally be observed outside of a trial setting, threatening the external validity of a trial (see below).

Although RCTs are regarded as the gold standard of research methods they are not without limitations. Threats to the validity of randomised controlled trials fall into one of two categories, internal validity and external validity (Thorogood & Britton, 1999). Internal validity refers to the extent to which the results of a trial are attributable to the intervention or treatment (Bowling, 1997). The main threat to internal validity is baseline differences in comparison groups. However, as discussed above this is minimised by randomly assigning subjects to treatment or control groups.

Other factors that could affect trial results include patient and clinician preferences (McPherson et al, 1997). If they agree to randomisation, it is possible that participants may still have a strong preference for one intervention over another. If randomised to their preferred intervention they may adhere more fully or experience enhanced psychological benefit. In health behaviour interventions the outcome is to a large extent dependent on the motivation of the subject. Motivation would be expected to increase if a subject received the treatment of choice and vice versa. One exercise intervention (Dunn et al, 1999) randomised subjects to either a membership at an exclusive health club or to group exercise counselling sessions. Adherence to randomisation was difficult as some

subjects were disappointed not be randomised to receive a health club membership (personal communication). One approach to avoid this disappointment is to use a Zelen randomisation design (Zelen, 1979). In this approach subjects are randomised prior to obtaining informed consent and then consent is only sought for those subjects randomised to the treatment. Patients in the control arm are not aware of their randomisation and therefore are not disappointed.

A similar problem can occur if the health professional responsible for delivering the trial has a preference for one treatment over another. In this case they may influence outcomes by delivering one treatment with a lot more conviction than the other. For example, in a trial comparing frequent moderate intensity physical activity to less frequent vigorous intensity, the exercise professional prescribing the exercise might feel strongly about the need to perform vigorous intensity physical activity in order to derive health benefits and may therefore be reluctant to limit his/her advice to moderate intensity. The net effect may be that there is in fact very little difference between treatments.

Potential biases resulting from patient or practitioner preferences can be minimised by keeping both subjects and health professionals ignorant to randomisation (Thorogood & Britton, 1999). This type of double blinded trial is most suited to drug trials where both the treatment drug and the placebo drug are identical apart from the active ingredient. In health behaviour interventions, double blinding is more difficult as the intervention often involves some kind of face to face advice. In a smoking cessation intervention for example, the subject could be randomised to individual counselling sessions to quit smoking or group counselling sessions. In this situation it is sometimes possible to keep the person measuring the outcomes blind to randomisation but not the subject. This is

known as a single blind trial (Bowling, 1997). In trials of health professionals' communication style it is possible to blind the patients to randomisation but not to blind the health professional.

The external validity of a trial refers to how well the results of a trial can be generalised to a wider population (Bowling, 1997). It has been argued that the process of randomisation and gaining consent may produce a sample of subjects unrepresentative of the wider community.

For example, as already pointed out above, subjects may have strong preferences for a particular kind of treatment and may refuse randomisation if they think they might get offered a treatment they would rather avoid. It has been observed that in treatment trials, those involving medical treatment for a pre-existing condition such as cancer treatment, participating subjects tend to be less affluent, less educated and more severely ill than non-participating subjects, which can lead to exaggerated treatment effects (McKee et al, 1999). The opposite appears to be true of behavioural and prevention trials i.e., hypertension control trials and health screening etc., where participating subjects tend to be more affluent, better educated and already lead a healthier lifestyle. This may lead to an underestimation of the effect of the intervention. To help account for these potential sources of bias it is important that whenever possible baseline data are collected on all eligible subjects including those who accept the intervention and those who do not. Differences between eligible subjects who accept randomisation and those who do not can then be reported and will give an indication of the generalisability of the results.

The method used for recruiting subjects can also influence the representativeness of study subjects. One study of exercise promotion compared the baseline characteristics of subjects recruited through advertisements to those recruited through a random digit dial

telephone survey. Those recruited via the telephone were more likely to be smokers and have other cardiovascular risk factors than those volunteers responding to advertisements (King et al, 1994). Subjects responding to radio and newspaper advertisements offering an exercise intervention are more likely to be more motivated to change than other those recruited more opportunistically.

Other threats to external validity include the use of highly skilled personnel delivering specialist treatments which are unlikely to be able to be replicated in normal practice. Efficacy trials are designed to examine whether an intervention works in those who receive it and are usually delivered in as near an ideal setting as possible (Jadad, 1998). An example would be a laboratory based trial of exercise and hypertension where the exercise prescription was very controlled by exercise professionals. Effectiveness trials, on the other hand, investigate whether an intervention works in those who are offered it and usually take place in a more naturalistic setting (Jadad, 1998). In practice, trials of health behaviour interventions usually fall somewhere between these two study designs.

The external and internal validity of a study can be reduced if there is a large and non-random loss to follow up. This can lead to differences in outcomes between groups that are not attributable to the intervention. This is a particular problem for health behaviour interventions which require strong commitment and resolve from subjects. If good baseline data are collected this problem can be partially adjusted for and examined in the analysis. The results of intention to treat analysis, which involves including all randomised subjects in the final analysis (even those lost to follow up) partly attenuates this problem.

Black (1996) has described other limitations of RCTs. He points out that RCTs are unable to measure infrequent adverse or beneficial events or long term outcomes. This is particularly relevant for health promotion research where the full effects of interventions are not normally observed for 20-30 years. He also observes that the various stakeholders involved in a trial may be unwilling to agree to randomisation either on ethical grounds or concerns over being compared to other professionals. When RCTs are not possible or practical, Black recommends the use of prospective cohort studies.

Tones (1998) has questioned the ethics of denying people health promotion by randomising them to a control group. This argument can only be true if we believed that all health promotion at least did some good, was certainly not harmful and that providing health promotion services was not using resources that could be used more effectively in some other way. Kleijnen et al. (1997) have observed that well meaning health professionals have "often inadvertently harmed those who have turned to them for help." A qualitative study of patients' perceptions of doctors' advice to quit smoking found that some smokers fed up with repeated advice from doctors were deterred from seeking medical advice when they needed it (Butler et al, 1998). Tones (1998) also believes that RCTs conflict with the ideology of health promotion because RCTs treat people as objects whereas health promotion requires them to be active participants and decision makers. Attempts have been made to include patient preferences in RCTs. One approach is to elicit patient preferences at the start of the trial for all subjects accepting randomisation and then examine the preferences in the final analysis (Torgerson, 1996). Preference trials include at least one group where subjects are free to select from a range of treatments or interventions (Jadad, 1998). Although these type of trials go someway to

resolving concerns over imposed interventions, they are unlikely to be completely acceptable to those with views similar to Tones.

For many health promotion interventions the target of the intervention is a community and the intervention itself a policy or environmental change. In these circumstances other research designs, such as before and after studies or prospective cohort studies (Hennekens, 1987), may be more appropriate.

In summary, when randomisation is possible and the intervention can be tightly controlled, randomised controlled trials are best positioned to answer questions regarding whether or not an intervention works. Other questions relating to why an intervention did or did not work or whether an intervention was well received by the subjects, are better answered using different research methodologies such as qualitative methods (Sackett & Wennberg, 1997).

Chapter 6 Methods

6.1 INTRODUCTION

The aim of the study was to assess the effectiveness of two contrasting interpersonal styles of communication to promote physical activity in insufficiently active, middle aged men and women. The study tested the following null hypotheses:

I. There would be no difference in levels of self-reported physical activity at 12 month follow up, in insufficiently active men and women aged 45-64 years, between intervention and control groups.

II. There would be no difference in levels of self-reported physical activity at 12 month follow up, in insufficiently active men and women aged 45-64 years, between a group receiving brief negotiation and a group receiving direct advice.

Sample size calculations

Original calculations were based on being able to detect a 7 kcals/kg/week difference between groups. Four hundred intervention subjects (200 per group) with complete data were required for analysis. However, concern was raised that the estimated effect size of 7 kcals/kg/week of additional leisure time physical activity was over optimistic and that a more realistic estimate was 5 kcals/kg/week. The sample size required to detect this difference with 90% power was 800 intervention subjects.

From early recruitment figures it was estimated that the actual sample size was likely to be around 260 per intervention group (allowing for a 10% loss to follow up). This would result in:

- 76% power to detect a difference of 5 kcals/kg/week.
- 97% power to detect a difference of 7 kcals/kg/week.

A comparison of the combined intervention groups (Brief Negotiation + Direct Advice) with the control group uses larger numbers of subjects and therefore has greater power: 87% power to detect a difference of 5 kcals/kg/week.

The co-ordination of the study was done by myself at the London School of Hygiene & Tropical Medicine in the Health Promotion Research Unit. Charlie Foster a health promotion and exercise specialist in Northampton was seconded to the project for 2.5 years to deliver all of the interventions and collect data from control subjects. Clerical duties including posting questionnaires, making appointments etc., were done by Gerald Dove on a part time basis for 3 years. He was based in Northampton Community Health Council offices where he was already working part time.

To assist in the management of the trial and the handling of incoming data, a Microsoft Access database was developed by Jan Dobbins, a data manager working elsewhere in the school. I used this for tracking subjects' progress through the trial and for entering data from baseline questionnaires. The database was also used to record attendance rates and to produce reports of people failing to return questionnaires and physical activity log books.

6.2 LOCATION & SETTING

The Move-It study was located in Wellingborough, Northamptonshire. In 1991 there were 67, 789 residents in Wellingborough (OPCS, 1992). Selected demographic data on the population is shown in Table 6.1. Just under half the population are male with 21% in the target age group. Seven per cent are non-white which is 1% higher than the national average of 6%, mainly as a result of the higher Indian population (OPCS, 1993). Forty

five percent of adults are in full time employment with 5% unemployed. Three per cent more people are in full time employment compared to national levels and there a 2% fewer households without a car. Overall, Wellingborough is reasonably representative of a national sample.

Table 6.1 Selected demographics of population of Wellingborough

Characteristic	**N = 67,789**	**% of Wellingborough population**	**% of English population**
Male	33,172	49	48
Aged 45-64 years	14,309	21	22
Ethnicity			
White	62,921	93	94
Indian	2,317	3	2
	Total aged 16 and over N = 53,297		
Married	32,733	61	58
Home owned/mortgaged	18,420	35	34
Full time employment	22,962	43	40
Unemployed	2,475	5	6
No car household	7,590	14	16

Apart from the fact that Wellingborough is a 'typical' middle England town, two other motives led to the trial being based there. The Director of Public Health for Northamptonshire, Dr. Jill Meara, was known to Dr. Margaret Thorogood of the London School of Hygiene and Tropical Medicine and Charlie Foster, mentioned in section 6.1, was known to myself. Both of these people were approached during the summer of 1995 and agreed to support the study.

Data from Northamptonshire Health Authority informed me that Gold Street Medical Centre in Wellingborough was large enough for me to recruit the required sample. In September 1995 Charlie Foster and I approached Gold Street Medical Centre about the

possibility of locating the trial there. Dr. David Lawrence, a partner, informed us that they were very short of room space and were planning to extend the building to include more consulting rooms. He felt that at that time the practice was already too congested to house the study. He pointed out that some of the General Practitioners (GPs) from the centre had already moved away to a new medical centre, The Redwell Medical Centre. He suggested we start our study there, if they were willing, and return to Gold Street the following year when he anticipated they would have completed building more consulting rooms.

David Winter, the Redwell Medical Centre manager, was contacted in November 1995 with a proposal to start the study at his centre. Following a presentation to all practice staff, permission was granted to commence the trial at Redwell at the start of 1996.

In August of 1996, Gold Street Medical Centre was approached for a second time. I was informed that a decision had been taken not to redevelop the existing premises but to relocate to a new building. Although staff would be moved to the new Albany House Medical Centre in the autumn, we were requested not to begin the second part of the study until January 1997. This delayed the study by 3 months.

6.3 ETHICS APPROVAL

Ethics approval was obtained for the study from Kettering Ethical/Research Committee on 22nd January 1996.

6.4 SUBJECTS

Cohort data, computer models of physical activity strategies and estimates of the cost effectiveness of physical activity strategies, have all argued that focusing interventions on those age over 45, would produce the greatest health gain, particularly in men (Nicholls et al 1994; Pate et al, 1995; Naidoo et al, 1997). As moderate intensity, unsupervised physical activity was to be recommended, an age limit of 64 was imposed based on existing safety guidelines (Shephard, 1988).

Following ethics approval a colleague, Wendy MacDowall, familiar with GP computer systems, travelled to Redwell Medical Centre with me to retrieve the records of subjects in the target age group 45-64 years. After some difficulty 2,910 records were retrieved of men and women registered at the practice who at that time were aged 45-64. Approximately a year later the exercise was repeated at Albany House Medical Centre where a further 2,887 records were retrieved. The two general practices provided a final sample of 5,797 subjects in the target age group 45-64. Baseline questionnaires (see section 6.6) were sent to all 5,797 subjects to identify those who were insufficiently active.

6.5 RANDOMISATION & INFORMED CONSENT

Insufficiently active subjects eligible for the trial were randomly assigned to one of three arms by Ian White, a medical statistician: (1) Direct Advice, (2) Brief Negotiation or (3) Control. Subjects were randomised by household in monthly batches. The households in each batch were randomised in equal numbers to the three arms. All individuals in the same household received the same allocation. The reason people were randomised by household was to ensure that a couple would not be randomised to different interventions.

As the trial is about opposing styles of intervention there is a risk of one person in a couple being dissatisfied with their intervention if they felt it was markedly different from their partners. This risked contamination of either of the interventions and may have reflected badly on the medical centre so was therefore avoided.

Subjects' group assignments were put into sealed envelopes and sent to the health promotion specialist, Charlie Foster, in Wellingborough. Subjects attending for their health check (see section 6.6) were informed at the start of the check that it was part of a trial. They were asked to give their informed consent to participate after reading a short information sheet about the trial (Appendix A). Subjects who did not consent still received a health check but were not contacted again. Once consent had been obtained, Charlie Foster opened the sealed envelope and proceeded with the health check and the appropriate intervention.

6.6 RECRUITMENT

Recruitment took place between February 1996 and May 1997. All 45-64 year old patients registered at both the Redwell Medical Centre and Albany House Medical Centre were sent a baseline lifestyle questionnaire. The questionnaire included items on drinking, smoking, eating and exercise as well as demographic information (Appendix B). The questionnaire was developed specifically for the study but used elements from pre-existing survey items such as the Health Survey for England (see section 6.9). The physical activity section of the questionnaire was adapted from one used in cohort studies (see section 6.9). Subjects who failed to return the questionnaire were sent a reminder letter and second questionnaire. If after this time the questionnaire was still not returned, these subjects received no further contact. Table 6.2 shows the return rate of baseline

questionnaires by month. Overall 73% of subjects returned their questionnaire with little variation in this proportion each month. The return rate was 48% with the first mail-out rising to 73% following one postal reminder. Most subjects returned their questionnaire within 2 months of it being sent out.

Table 6.2 Baseline questionnaire return rates by month

	Baseline Questionnaires Sent Out										
	1996						1997				
	Feb	Apr	Jun	Jul	Aug	Sep	Jan	Feb	Mar	Apr	**Total**
Sent Out	**300**	**500**	**500**	**500**	**500**	**610**	**650**	**700**	**700**	**837**	**5797**
Returned											
Mar	173										**173**
Apr	47										**220**
May	7	239									**466**
June		79	263								**808**
July		27	96	284							**1215**
Aug			9	10	13						**1247**
Sep			3	77	313	280					**1920**
Oct			1		33	131					**2085**
Nov					1	56					**2142**
Jan							233				**2375**
Feb							182	24			**2581**
Mar							52	377	326		**3336**
Apr							3	98	36	118	**3591**
May								6	120	297	**4014**
Jun							1	2	19	169	**4205**
Jul	1							2	1	5	**4214**
Aug									1		**4215**
Total N	**228**	**345**	**372**	**371**	**360**	**467**	**471**	**509**	**503**	**589**	**4215**
% return	**76**	**69**	**74**	**74**	**72**	**77**	**72**	**73**	**72**	**70**	**73**

Subjects were excluded from the trial if they had a long standing illness, disability or infirmity which would prevent participation in moderate intensity physical activity. The decision to exclude people was based on their responses to questions 2 and 27 in the baseline questionnaire.

Q2. Do you have a long-standing illness, disability or infirmity? (By longstanding we mean anything that has troubled you over a period of time or that is likely to affect you over a period of time).

Q27. Which of the following best describes your current situation?

> Permanently sick or disabled and not able to work.
> (all other items in this question related to work status)

The main reasons for exclusion were pre existing cardiovascular disease or orthopaedic conditions which restricted the ability to walk without undue pain or discomfort. The full list of exclusions is in Chapter 7, Results. Responses to question 2 were crossed checked with question 19, which asks about the person's ability to walk a mile without pain or discomfort. Subjects who responded positively to question 2 but who reported that they could walk a mile without pain were referred to their GP for a final decision about inclusion in the trial. If any doubt existed about a subject's eligibility on medical grounds they were also referred to their GP. One hundred and eighteen subjects were referred back to their GP, 40 of whom were subsequently excluded from the study.

Subjects returning questionnaires were divided into Active or Insufficiently Active groups. Insufficiently active subjects were classified as such if they responded 'No' to questions 11 and 12 in the baseline questionnaire which meant that they:

- did not regularly take exercise to improve/maintain their health and/or fitness.
- had not done physical activity during their leisure time (excluding physical activity at work and in the home) at least once per week for a minimum of 30 minutes each time during the past 4 weeks.

This simple filter procedure was used in preference to the physical activity recall section of the questionnaire because attempting to code and classify the recall items would have led to a long delay between baseline questionnaires being returned and the invitation to attend the intervention. One thousand nine hundred and six subjects (45% of those returning questionnaires) were classified as insufficiently active.

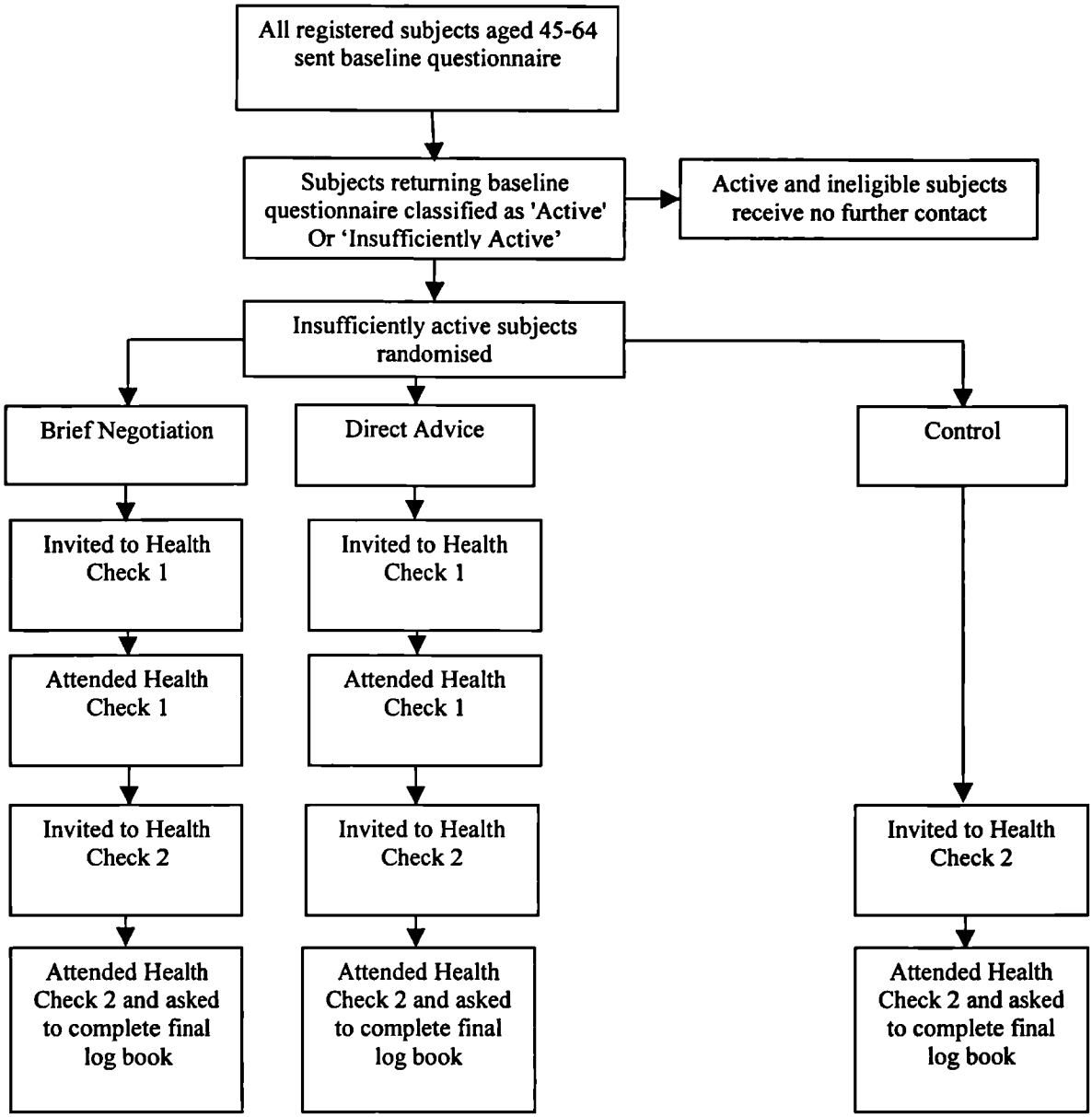
The 2,309 subjects deemed to be already active by this method received no further contact.

Following medical exclusions (n=248) all insufficiently active subjects were sent to Ian White, a Medical Statistician advising the study, for randomisation. One thousand and ninety five subjects were randomly allocated to either the direct advice or brief negotiation groups. They were invited, by post, to attend for a routine health check. The cover letter intentionally made no mention of physical activity to avoid recruiting physical activity volunteers (Appendix C). A further 563 no intervention control subjects received no further contact at this time.

Invitations to the health check were sent out by Gerald Dove, the project clerk, with set appointment times. Subjects were given Gerald's number to call if they were unable to attend the health check or wished to change the appointment. The onus to break the appointment was placed on the subjects intentionally. Experience from an earlier trial had showed that if the responsibility for initiating an appointment is on the subjects then only 35% attendance is achieved (Stevens et al, 1998).

Subjects failing to attend for their health check were sent a postal reminder (Appendix D) with a new appointment. If they failed to attend for a second time no further contact was attempted. Six hundred and ninety seven subjects (53% of those invited) attended for a health check between 5th May 1996 and 2nd October 1997. Of those, 59% attended first time with the remaining 283 attending after postal reminders. The average period between the return of the baseline questionnaire and attendance at the health check was 57 days ($\pm$28 days). A summary of the recruitment procedure can be found in Figure 6.1.

Figure 6.1. Recruitment procedure



6.7 DESCRIPTION OF INTERVENTION AND CONTROL CONDITIONS

Brief negotiation

The brief negotiation arm of the trial was based on the principles of Motivational Interviewing. Motivational interviewing was developed in the areas of drug and alcohol in the early eighties and is a client centred approach to motivating clients towards behaviour change. (Miller & Rollnick 1991). It realises that most people are ambivalent about behaviour change and vary in their readiness or motivation to change. It has been defined as "*a directive, client-centred counselling style for eliciting behaviour change by helping clients explore and resolve ambivalence*" (Rollnick & Miller, 1995). Its central purpose is the examination and resolution of ambivalence, which it sees as a key obstacle to change. In this context, ambivalence refers to a persons psychological conflict about choosing between two courses of action such as taking up regular exercise or staying inactive. When people are very ambivalent they often become immobilised and stuck in a state of contemplation not action.

Resolving ambivalence is often difficult because the alternative courses of action each have advantages and disadvantages. Apart from the stages of change model, other conceptual models have also influenced the development of motivational interviewing. They include reactance theory and self-regulation theory. Reactance theory posits that perceived threats to personal freedom and choice elicit behaviours designed to demonstrate and restore freedom. Self-regulation theory suggests that behaviour is regulated by cycles involving the monitoring of one's own status, comparison of status with expectations and 'course correction' when status does not match expectation. Motivational interviewing, as originally described, is suited for specialist settings not restricted by time. A more structured, time limited version has been suggested for non-

specialist settings. Brief motivational interviewing has been proposed for use by general health care workers and was designed with the following considerations in mind. It should be useable in time limited consultations; the training of practitioners should take no more than 12-15 hours; interviews should be able to raise the subject of behaviour change in a sensitive and respectful manner, and the method itself should be flexible and capable of being used with subjects who vary in their readiness to change (Rollnick et al, 1992).

Brief motivational interviewing was adapted for use in this trial with the assistance of Dr. Steve Rollnick. A menu of strategies, based on those first described in the Rollnick paper, was developed for the 30 minute brief negotiation arm of the study. Each strategy is suitable for a different level of motivation or readiness. They are:

1. Feedback about current physical activity versus recommendations
2. Assessment of motivation and confidence
3. Weighing up the pros and cons
4. Information giving
5. Exploring concerns
6. Helping with decision making

A description of each of the strategies was prepared and used for training purposes (Appendix E). Consultations with subjects in the Move-It study worked through the strategies at a pace dictated by the subject. It was not the aim of every consultation to take clients from strategy 1 through to 6. The style of working is characterised by its lack of instruction about changing physical activity.

Direct advice giving

Giving advice is generally the approach to behaviour change adopted in primary care and might be regarded as 'usual care'. The premise behind this approach is that people do not engage in 'healthy' behaviours or continue with 'unhealthy' behaviours due to a lack of information and are more likely to change their behaviour if they receive information from a respected source. In this type of encounter the health professional attempts to convince the patient about the existence of a problem behaviour, e.g., smoking, excessive drinking, lack of physical activity. They then offer direct advice about the need to change and use external contingencies (e.g., threatened future ill health) to coerce the client into change. Some evidence for this approach has been provided in the area of smoking cessation, where direct advice to stop smoking from a doctor seems to result in success rates of approximately 2% (Thorogood, 1999). Some preliminary studies of the effect of doctor's advice about exercise have indicated that this approach may also be beneficial for exercise promotion at least in the short term (Lewis & Lynch, 1993; Calfas et al, 1996). The underpinning theory for this approach, although not often made explicit, is the health belief model. Subjects in the Move-It study were given information and advice about the health benefits of physical activity, the health risks of low physical activity, and were given the current recommendation for moderate intensity physical activity, namely brisk walking. The guidance for the direct advice subjects is in Appendix E.
The differences between the two approaches are shown in Table 6.3.

Control

Control subjects received no contact until the 11 month follow up health check. Until this time they were not aware that they were in the study, only that they had been asked to complete a questionnaire. At the follow up health check they only had their height, weight

and blood pressure measured and were asked to complete the log book. They received no other intervention.

Table 6.3. Direct Advice vs. Brief Negotiation

	DIRECT ADVICE	BRIEF NEGOTIATION
Purpose of appointment	To persuade client to increase physical activity level	To explore ambivalence about increasing physical activity and build motivation for change
View of participant	Someone at increased risk of CVD due to presence of a major risk factor (physical inactivity)	Someone who feels two ways about taking up regular physical activity and is not ready to change
Task of practitioner	Persuade person to adopt a programme of daily brisk walks and thereby reduce CVD risk	Explore pros and cons of regular physical activity and if appropriate, concerns about physical inactivity. Build motivation and confidence for change
Information exchange	Present evidence about risks of inactivity and benefits of increased physical activity, plus prescription of brisk walking as 'treatment'	Present information neutrally about current activity level compared to recommended level and elicit personal reaction
Type of questions used	Ask questions to elicit any existing harm resulting from inactivity which might be used to persuade client to change. Ask questions about possible ways of increasing physical activity	Open ended questions which encourage client to explore pros and cons of increased physical activity and remaining insufficiently active
Summary of appointment	Dangers of physical inactivity benefits of change and how to change	Summarises all sides of ambivalence using client's language and elicit client's response
Resistance	Met with counter arguments and correction	Met with reflection - a sign that practitioner is moving too fast.

Potential Confounding by Therapist Effect

Charlie Foster, who has formal training in exercise science and has been trained in brief motivational interviewing, delivered both interventions in an attempt to avoid any 'therapist effect'. In other words, if two practitioners were used it might be that any observed effect could be accounted for by subjects having a preference for one practitioner over the other. Both interventions were rehearsed to ensure accuracy and also to make sure that each one lasted for the allocated 30 minute time period.

Further Intervention

All intervention subjects received further intervention via the telephone at the following intervals (weeks):

2, 6, 10, 18, 26, 34

The content of the conversation was consistent with randomisation, with subjects assigned to direct advice receiving more advice about the importance of exercise and those in the brief negotiation group receiving more negotiation. Subjects without telephones (9%) did not receive this follow up. The telephone contact was intended to be no longer than 5 minutes' duration per call.

Self-monitoring

In addition to follow up contact via the telephone, all consenting intervention subjects were asked to engage in self-monitoring of their physical activity. All consenting intervention subjects were sent in the post a 7 day physical activity log book, at 3, 6 and 9 months post intervention (see section 6.9). A sample of one page can be found in Appendix F. Each page of the log book represented one day of the week and each item was identical to the physical activity items in the baseline questionnaire. Those subjects

who failed to return log books were sent one postal reminder to return them 4 weeks after they were sent out.

6.8 FOLLOW UP

At month 11 (11 months after Health Check 1) 546 intervention and 561 control subjects were invited by mail (Appendix G) for a follow up health check: Health Check 2 (Health Check 1 for Control subjects). Those failing to attend were sent up to two written reminders (Appendix H) and if necessary a final telephone reminder before assuming they were lost to follow up.

Four hundred and eleven intervention subjects attended, 75% of those invited, while 408 controls attended (73%). Repeat measures of height, weight and blood pressure were taken. No further intervention was delivered during this health check.

Control subjects were asked for informed consent at the beginning of the health check in the same manner as intervention subjects were 11 months earlier, although they were consenting to less. Only 8 control subjects failed to consent. Once they had consented they then had the same measures taken as intervention subjects.

At the end of the health check, all subjects were handed the final 4-week (28 day) physical activity log book. The log book was identical to the interim ones (Appendix F) apart from the number of days. Subjects were requested to return the log book by post in a pre paid envelope. Subjects failing to return their log books were sent two postal reminders and additional copies of the log book. The mean follow up period, calculated as the number of months between the baseline measure of physical activity and the final

measure, was 14 months (± 2.5 months). Eighty six percent of intervention subjects returned their final physical activity log book compared to 80% of control subejcts.

6.9 MEASUREMENTS

Measures of physical activity

The physical activity section of the baseline questionnaire was adapted from the Minnesota Leisure Time Activity Questionnaire. This physical activity frequency questionnaire was developed for The Multiple Risk Factor Intervention Trial (MRFIT) which studied the relation of leisure time physical activity to first major CHD event and overall mortality (Taylor et al, 1978; Leon et al, 1987). The decision to use an adapted version of this questionnaire was based mainly on the observations of Davey Smith and Morris (1992) who proposed that a check list of physical activities was more reliable than the recall of broad categories of physical activity. In addition, the advantages of recording the frequency of specific activities gives the greatest flexibility in analysis and does not require subjects to make any decisions about whether or not to include an activity such as is the case when they are asked to recall occasions of moderate or vigorous physical activity. More detailed discussion of methods of assessing physical activity is in Chapter 5, Methodology.

In the original questionnaire individuals were asked to record the frequency with which they had performed any of 64 separate activities for each of the previous 12 months. For this study, a 12 month intervention study, a recall period of 12 months was too long for measuring changes in physical activity. Therefore, I decided that a recall period of 4 weeks was more appropriate as this period has been used successfully in the Allied Dunbar National Fitness Survey and the Health Survey for England. The original 12

month questionnaire has already been used in this shorter reference period as part of an evaluation of a range of commonly used physical activity questionnaires (Jacobs et al, 1993). I also decided that the number of items in the MRFIT questionnaire were too many. This mainly reflected the difference in study populations. Few of our 45-64 year old subjects were likely to regularly engage in activities such as scuba diving or touch football. The physical activities included in the Move-It questionnaire were selected from the 1996 General Household Survey which lists physical activities by their popularity. In other words I attempted to select activities that were most likely to be performed by our study population and account for the greatest proportion of leisure time physical activity and activities of daily living. Under each general type of activity an 'Other' section was provided to allow people to write in activities that they had performed that were not in the list. The first 300 questionnaires that were sent out were looked at in detail for reported activities written in the Other sections to see if any justified being entered as an additional item. This was not the case, the questionnaire captured the main activities that people performed regularly. The only change made to the questionnaire was an alteration in the layout to make it slightly easier on the eye.

Physical activity was calculated as total energy expenditure in kilocalories/kilogram bodyweight/week. Each activity in the questionnaire was assigned a MET value (Metabolic Equivalent) from published sources and personal communication with Professors Ralph Paffenbarger and Jerry Morris.

They are presented in Table 6.4 below. Kilocalories per kilogram bodyweight per week were calculated using the following formula:

Frequency X Duration X Intensity / 4

Frequency = Number of occasions in 4 weeks

Duration = Total number of hours in 4 weeks

Intensity = MET* value of activity

*1 MET is equivalent to 1kcal/kg/hour

The MET values used were either taken from Ainsworth et al (1993) or from the Harvard Alumni study. The Harvard coding system was provided by I-Min Lee, on behalf of Professor Paffenbarger, who had recently finished extensive revision of the original tables. Final decisions were taken after discussions with Professor Jerry Morris.

Table 6.4. MET values for physical activity

ACTIVITY [CODE]	SOURCE - CODE*	METS	INTENSITY†
Gardening			
Hoeing, weeding, pruning	A08050	5.0	M
Mowing with power mower	P159	4.5	M
Mowing with hand mower	P158	6.0	V
Planting flowers seeds	A08140	4.0	M
Digging, clear rough ground	P167	5.0	M
Other heavy gardening	A162	5.0	M
Walking			
Walking at slow pace	P001	2.0	L
Walking at average pace	P004	3.5	M
Walking at fairly brisk pace	P005	4.0	M
Walking at fast pace	A17220	4.5	M
Walking with heavy shopping	P239/P237	3.0/4.5‡	M/M
DIY			
General building work	A06050	6.0	V
Decorating	P194/P195	4.5/5.0‡	M/M
Minor household repairs	A06240	3.0	M
Car washing & polishing	P184	4.5	M
Car repairs & maintenance	P183	4.0	M
Other	As for gardening	5.0	M
Home			
Bedmaking	P202	2.0	L
Moving heavy furniture	A05120	6.0	V
Spring cleaning	A05040/A05030	2.5/3.5‡	L/M
Cleaning windows	P263	4.5	M
Hovering	P204	2.5	L
Dusting	A05040	2.5	L
Washing floors	P263	4.5	M
Other		2.5	L
Sport & Recreation			
Aerobics/keep fit	P031 P032	6.0 7.0‡	V/V
Dancing	P027/P028	3.5/4.5‡	M/M
Swimming	P082/P083	6.0/8.0‡	V/V
Running/jogging	P058/P060	6.0 8.0‡	V/V
Football/rugby	P140	7.0	V
Badminton	P104	4.5	M
Tennis	P148	7.0	V
Golf	P124	4.5	M
Yoga	A02100	4.0	M
Cycling	P014 P016	6.0 8.0‡	V/V
Other (code specifically) Bowls Walking Squash All others	 P111 P004 P146	 3.0 3.5 12.0 6.0	 M M V V

*A–Ainsworth; P Paffenbarger; † MET intensity; L = light (< 3 MET); M = moderate (3-5.9 MET)
V = vigourous (>–6.0 MET); ‡ MET value split on basis of reported intensity
(higher MET value taken if subject reported that the activity usually made them 'breathe hard')

The 3, 6, 9 and 12 month physical activity log books were exact replicas of the physical activity questionnaire items. The only difference between these log books and the baseline questionnaire was the referent period. In the baseline questionnaire the referent period was a recall of the previous 28 days. In the 3, 6, and 9 month log books (which were used as self-monitoring tools) the referent period was 7 days. Subjects were requested to complete each page (one page per day) of the log book at the end of that particular day. The final log book was for 28 days and provided the main outcome measure of physical activity. The coding and energy expenditure calculations of the log books was the same as those used for the baseline questionnaire.

Validation of Physical Activity Log book

A subset of 56 subjects wore portable motion sensors (accelerometers) to corroborate their self-reported physical activity. They were worn during the first week of the final 4 week log book. The Tritrac accelerometer (Hemokinetics, Madison, WI) senses acceleration in three separate directions: vertical, lateral-medial and anterior-posterior and converts the data into kilocalories/5 minutes. Each Tritrac device was initialised by CF on the day of issue, via a computer interface, with the subjects height, weight and gender. The subjects were asked to wear the device around their waist during waking hours with a Velcro fastening belt that was provided.

Subjects were requested to return the devices to the medical centre after 7 days. The data collected from each device was uploaded onto a computer and saved in an Excel spreadsheet. Energy expenditure in kilocalories is provided in 5 minute blocks (kcals/5min) by time of day. As date and time are recorded, the data can be compared to self reported physical activity, and this was done using the method described by Bland and Altman (1986).

Anthropometric and Clinical Measures

All subjects attending Health Check 1 (intervention only) who consented to the study, had their height, weight and resting blood pressure recorded. Weight was measured using a doctor's scale with subjects wearing indoor clothing and without shoes. Resting blood pressure was measured using a Hawksley random zero mercury sphygmomanometer. Measurements were taken twice after at least 5 minutes of sitting at rest. The average of the two readings was recorded. These measures were repeated at the second health check 11 months later for intervention subjects and collected for the first time from control subjects.

Additional measures

Potential confounding factors collected in the baseline questionnaire are presented in Table 6.5.

Table 6.5 Baseline variables

Variable	Type of variable
Age	Continuous
Gender Male/Female	Categorical
Married or living as married	Dichotomous
Home ownership Owned/mortgaged	Dichotomous
Education Degree or equivalent A level O level Other None	Categorical
Employment status Full/part time Retired Unemployed Others	Categorical
Car ownership	Dichotomous
Physical health Permanently sick/disabled Long standing illness No physical limitation	Categorical
General health Bad Fair Good	Categorical
Readiness to change quintiles	Categorical
Alcohol units/week	Continuous
Smoker	Dichotomous

All of the items above, apart from the Readiness to Change measure, were adapted from items used in the Health Survey for England. Personal communication with staff at the Office of National Statistics provided information about which Health Survey items worked best in a self-completion questionnaire rather than a face-to-face interview which the survey uses. The staff had been piloting the items for an NHS survey which was never implemented.

The Readiness to Change measure was developed by myself, Dr. Steve Rollnick from University of Wales School of Medicine and Dr. Rick Budd from the Department of Clinical Psychology, Whitchurch Hospital, Cardiff. The questionnaire was originally developed for use as part of the Health Education Authority's Active for Life Panel Survey. The questionnaire items are a modified subset of those contained in the Readiness to Change Questionnaire which assesses a person's readiness to reduce their alcohol consumption (Heather et al, 1993). The modified items were designed to assess the Precontemplation, Contemplation and Preparation stages of the Transtheoretical Model (Prochaska et al, 1992).

Data from the HEA survey was collected on this measure for 6,045 subjects. The psychometric properties of the scale were assessed by Dr. Budd. The results of his factor analysis revealed that the items on the scale combine to form a reliable, homogeneous scale. He concluded that the scale is best treated as a unidimensional continuous measure of readiness to change rather than a measure of three separate stages of change. The results are in line with those reported by Budd & Rollnick (1996) who showed that, in a sample of excessive drinkers, the Readiness to Change Questionnaire was best construed as a continuous measure of readiness to change. The final nine item measure is shown in item 18 of the baseline questionnaire (Appendix B).

6.10 STATISTICAL METHODS

The distribution of energy expenditure values at baseline and follow up was skewed. Therefore, both measures were transformed by adding 1 and taking the logarithm: this improved the Normality of the distribution. Adding 1 was necessary because some subjects reported zero energy expenditure at baseline.

Comparisons of intervention versus control were based on all randomised subjects (target population 1), that is all those who were invited to the first health check. Comparisons of brief negotiation versus direct advice were based on all subjects who attended the first health check and consented to the study (target population 2), since allocation to brief negotiation or direct advice was concealed until this point. Except where otherwise stated, analyses were by intention-to-treat in these two target populations.

Substantial numbers of subjects had missing energy expenditure at follow-up, 68% of intervention subjects versus 43% of controls. Due to the large increase in energy expenditure in the control group between baseline and follow-up, it was inappropriate to carry the baseline observation forward. Instead, we constructed a regression model to predict follow-up energy expenditure in the absence of intervention, and used this model to impute follow-up energy expenditure for all subjects who did not complete the final log book. The model was constructed by a stepwise procedure using subjects in the control arm only. The outcome was follow-up energy expenditure, and the predictor variables were the baseline variables listed in Table 6.5 above, together with transformed baseline energy expenditure and an indicator of baseline energy expenditure being zero (to allow for the possibility that zeroes were miss-reported).

Imputing predicted values in this way tends to underestimate the variance and hence to underestimate standard errors (Little & Rubin, 1987). By a simple extension of Little and Rubin, page 46, we corrected all regression standard errors by multiplying by a factor $\sqrt{(1+\frac{n_I}{n-p}\frac{V_I}{V_R})}$ where n_I is the number of subjects imputed, n is the total number of subjects, p is the number of parameters in the regression model, V_I is the residual variance in the imputation model, and V_R is the residual variance in the regression model.

An analysis of covariance model was constructed by a stepwise procedure using subjects in all three arms and the baseline variables listed above (Table 6.5). Randomised allocation was entered into the models only after the model had been selected.

Baseline measures of blood pressure and body mass index were only available for subjects in the intervention arms who attended and consented to the study (n=585). Therefore, we only compared brief negotiation versus direct advice for these outcomes. The procedure described above for imputing missing values, based on the model constructed from control subjects, could not be applied here as control subjects did not have blood pressure or body mass index recorded. Therefore missing values were imputed by carrying baseline values forward . Standard errors were again inflated using the method described above.

Ancova analyses assume that all subject observations are independent. However, there were 1658 individuals randomised from just 1198 households. One way Anova revealed an intra-household correlation of 0.42. The conservative t-deflator means that in the main analyses t values should be divided by 1.06. This suggests that household clustering is unimportant but to make sure, the main analyses were repeated using robust standard errors which relaxes the assumption that observations are independent. Its only requirement is that observations are independent across the clusters, which in this case means subjects living in different households (Stata Press, 1997). This did not effect the main results and therefore the main results are reported for individuals.

Analyses were carried out using either SPSS for Windows version 7.5 (Norusis, 1998) or STATA 5 (Stata Press, 1997).

6.11 QUALITY CONTROL

All interventions were audio taped with permission. The purpose was to ensure that there was genuinely a difference between the two treatments and that the intervention protocol was adhered to. Very polite advice giving may be similar to poorly delivered brief negotiation. A random sample of 30 tapes were listened to by myself and Daran Woodward, who was not involved in the study but who is familiar with exercise interventions. Both of us were blind to the persons' randomisation. The tapes were wound forward to approximately half way and listened to until the listener felt able to state which treatment group the subject was in. A this point the listener recorded a '1' for Brief Negotiation and a '2' for Direct Advice. The inter-rater agreement between us was evaluated using the Kappa-statistic. The tapes also give us the opportunity to assess the intensity of how each of the interventions were delivered. A preference by Charlie Foster for either of the interventions may have led to him delivering the preferred one with greater commitment. However, suitable methods to assess the intensity of the interventions are not currently available.

Chapter 7 Results

7.1 RECRUITMENT

The progress of subjects through the different stages of the study is shown in Figure 7.1. Seventy three percent of the 5,797 subjects in the target age group returned baseline questionnaires. Age and gender differences of those returning questionnaires are shown in Table 7.1. Return rates were 16.5% higher in the oldest compared to the youngest age group and 7.8% higher in women compared to men.

Table 7.1 Comparison of age and gender of subjects returning the baseline questionnaire

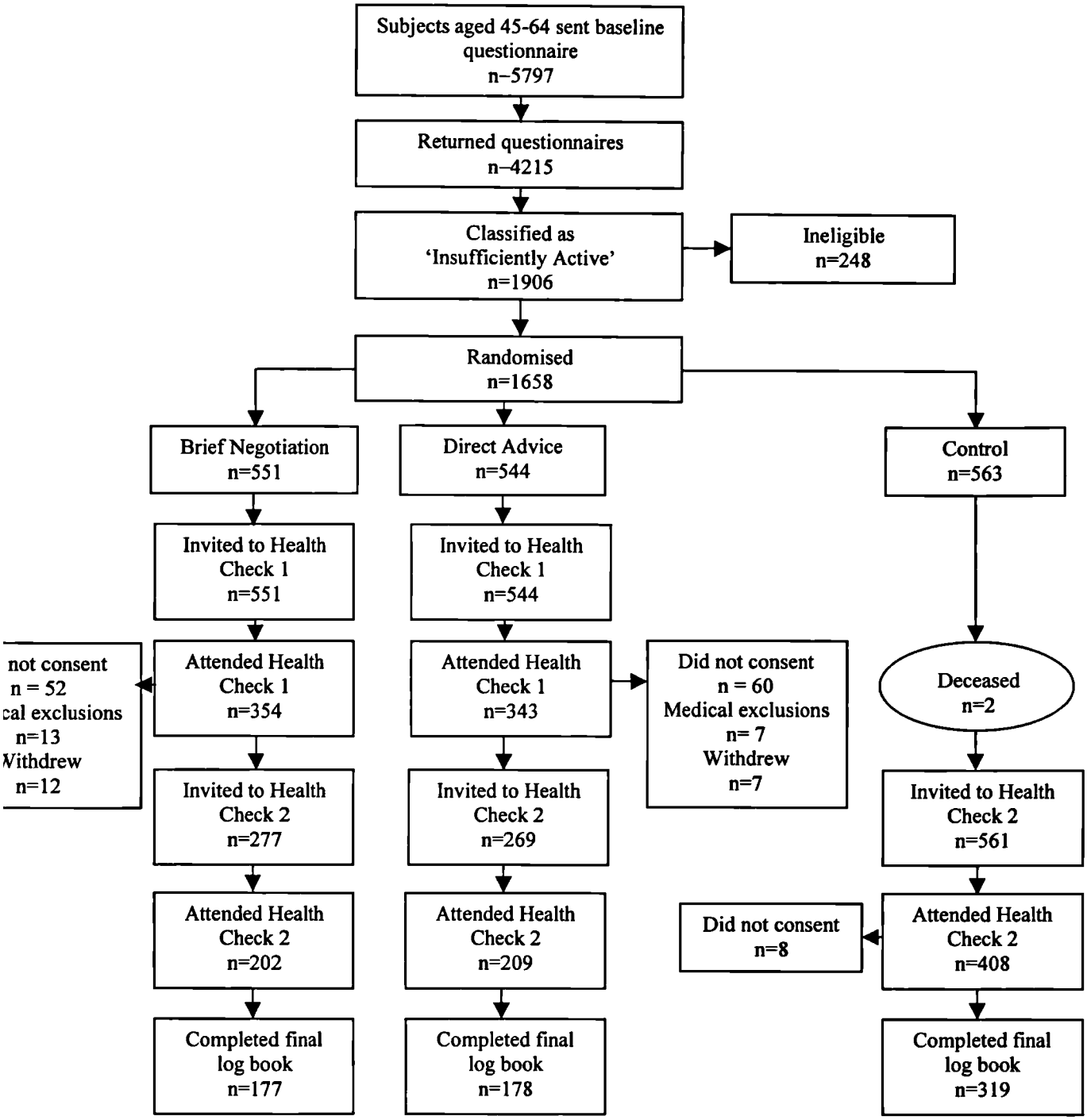
Characteristic	Returned questionnaire N=4215 (73%)	Did not return questionnaire N=1582 (27%)	P value
Age group %			<0.001
45-49	67.3	32.7	
50-54	68.7	31.3	
55-59	75.8	24.2	
60-64	79.5	20.5	
65-69	83.8	16.3	
Women %	76.5	23.5	<0.001
Men %	68.7	31.3	

Of those who returned the baseline questionnaire, 1906 were classified as 'Insufficiently Active', that is they responded no to both questions 11 and 12 in the baseline questionnaire.

Q11. Do you regularly take exercise to improve/maintain your health and/or fitness?

Q12. During the **PAST FOUR WEEKS** have you taken any exercise ***in your leisure time*** (i.e. apart from the physical activity in your job and/or at home) at least once a week for as long as 30 minutes - or 2 periods adding up to 30 minutes?

Figure 7.1. Flow of subjects through study



Two hundred and forty eight subjects were ineligible based on study medical exclusions. A summary of the exclusions are shown in Table 7.2.

Table 7.2 Medical exclusions by condition

Condition	Frequency
angina	18
arthritis	37
blind	1
cancer	12
cerebral palsy	3
CHD	33
circulatory	5
crohns disease	1
deaf	2
disabled	10
diverticulitis	3
hypertension	1
muscular dystrophy	2
chronic fatigue syndrome	3
metabolic	10
multiple sclerosis	11
musculoskeletal	1
orthopaedic	41
parkinsons	4
polio	4
psychiatric	10
renal failure	3
respiratory	19
stroke	7
requested no further contact	7
Total	**248**

The remaining 1658 subjects were randomised into one of the three arms of the study. Tables 7.3-7.6 compare the characteristics of those randomised versus those who were not. Randomised subjects were more likely to be men, non-white, poorly educated, employed, without physical limitations and smokers. They rate their health as at least fair and engage in low levels of physical activity compared to non-randomised subjects. Most of the differences observed are associated with low physical activity, the main inclusion criteria.

Table 7.3. Comparison of demographic characteristics of subjects randomised and those who were not

Characteristic	Randomised N=1658 (39%)	Not randomised N=2557 (61%)	P value*
Age group %			0.53
45-49	39.2	60.8	
50-54	40.2	59.8	
55-59	40.7	59.3	
60-64	39.0	61.0	
65-69	44.9	55.1	
Women %	37.4	62.6	0.004
Men %	41.6	58.4	
Married/living as married %	39.3	60.2	0.92
All other %	39.5	60.5	
Ethnicity			
White %	38.9	61.1	0.06
Non-white %	44.1	55.9	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.4. Comparison of socio-economic characteristics of subjects randomised and those who were not

Characteristic	Randomised N=1658 (39%)	Not randomised N=2557 (61%)	P value*
Education %			<0.001
Higher qual.	28.0	72.0	
A level	31.8	68.2	
O level	34.8	65.2	
Other	38.6	61.4	
None	46.7	53.3	
Employment status			
Full/Part time %	42.2	57.8	<0.001
All other %	33.2	66.8	
Car ownership			
Yes	39.5	60.5	0.80
No	38.1	61.9	
Home ownership			0.64
Owned/mortgaged %	39.0	61.0	
All other %	40.8	59.2	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.5. Comparison of health measures of subjects randomised and those who were not

Characteristic	Randomised N=1658 (39%)	Not randomised N=2557 (61%)	P value*
Physical health			<0.001
Permanently sick/disabled %	27.2	72.8	
Long standing illness %	35.1	64.9	
No physical limitations %	60.3	39.7	
General health			<0.001
Bad %	23.8	76.2	
Fair %	43.5	56.5	
Good %	38.9	61.1	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.6. Comparison of health behaviour/psychological characteristics subjects randomised and those who were not

Characteristic	Randomised N=1658 (39%)	Not randomised N=2557 (61%)	P value*
Smoker %	45.0	55.0	<0.001
Non-smoker %	37.6	62.4	
Energy expenditure † kcals/kg/week (mean)	9.0	15.6	<0.001
No occasions of moderate or vigorous physical activity %	44.9	55.1	0.02
≥1 occasion of moderate or vigorous physical activity %	38.8	61.2	
Alcohol units/week (mean)	7.0	7.1	0.63
Readiness to change %			0.37
Low = 1	46.3	53.7	
2	47.0	53.0	
3	46.6	53.4	
4	43.7	56.3	
High = 5	45.2	54.8	

*P values are χ^2 for trend , χ^2 or t-test as appropriate. † Sum of moderate and vigorous intensity physical activity.

Subjects randomised to either of the two intervention arms were invited to the routine health check. Sixty four percent of brief negotiation subjects and 63% of direct advice attended for a health check. A total of 112 intervention subjects did not consent to the

study resulting in 585 subjects (10.1% of all registered patients in the target age group and 53% of those invited) receiving an intervention, 302 brief negotiation and 283 direct advice.

During the following 11 months prior to follow up 20 subjects withdrew for medical reasons (13 brief negotiation and 7 direct advice) and 19 asked to be withdrawn for non-specific reasons (12 brief negotiation and 7 direct advice). Therefore, 277 brief negotiation subjects and 269 direct advice subjects were invited to return for a follow up health check at 11 months post intervention. Seventy five percent of those invited to the follow up health check attended (73% brief negotiation and 78% direct advice). Final log book data was provided by 59% of consenting brief negotiation subjects and 63% of consenting direct advice subjects.

Two subjects randomised to the control group died prior to the health check stage of the study and were therefore not invited. Four hundred control subjects attended and consented to the study at the follow up health check (71%) and 80% of those who consented provided final log book data.

Table 7.7 shows descriptive baseline data by randomised group. No major differences exist between groups on any of these characteristics. A high proportion of subjects had no formal qualifications although most were in part time or full time employment. The majority of subjects owned a car and their own home. Approximately a quarter of randomised subjects were smokers which is lower than the national average and suggests that smokers were less likely to return their questionnaire. The mean energy expenditure of all randomised subjects was 9.0 kcals/kg/week which is equivalent to 630 kcals per

week for a person weighing 70kg. Although around a third of subjects reported some type of long standing illness (Question 2 of the baseline questionnaire), 71% rating their health as 'Good'. The mean readiness to change score across groups was 19 (range = 0-36) indicating that those randomised were not all highly motivated for exercise.

Table 7.7. Selected baseline characteristics by randomised group†

Characteristic	**Brief Negotiation**	**Direct Advice**	**Control**
N	551	544	563
Age, years	54.6 (5.5)	55.0 (5.9)	55.0 (5.7)
Men %	46.8	49.8	50.3
Married/living as married %	81.1	76.8	78.3
Ethnicity			
Non-white %	8.3	10.8	9.1
Education %			
Higher qualification	11.8	10.1	9.1
A level or equivalent	4.4	3.9	5.9
O level or equivalent	13.8	10.8	14.2
Other	20.0	23.2	22.2
None	44.3	46.3	43.9
Employment status %			
Full/part time	74.2	73.2	73.0
Retired	9.3	11.6	10.8
Unemployed	3.1	2.2	2.7
Others	13.4	13.1	13.3
Car ownership %	87.8	85.3	84.5
Home ownership %			
Owned/mortgaged	80.2	78.5	81.2
Smokers %	22.3	26.3	27.9
Energy expenditure kcals/kg/week	8.8 (2.5)	9.2 (2.4)	9.1 (2.2)
Alcohol, units per week	5.9 (10.0)	7.9 (12.5)	7.1 (13.5)
Physical health %			
Permanently sick/ disabled	6.2	4.8	4.4
Long standing illness	33.4	33.6	34.5
No physical limitations	59.7	60.8	60.2
General health %			
Good	69.7	72.1	72.1
Fair	26.0	24.6	24.9
Bad	2.9	2.6	2.4
Readiness to change	20.0 (6.9)	19.6 (6.8)	19.8 (6.7)

† Values are means (Standard Deviation) unless stated otherwise.

Differences between intervention subjects who attended and consented to the study and those who failed to attend are shown in Tables 7.8-7.11. Univariate analysis shows that attenders were more likely to be women, home owners and those who perceived their health to be good. Although there is a significant difference in alcohol intake between attenders and non-attenders, with non-attenders drinking just under 2 units a week more, both groups were drinking well below recommended levels.

Table 7.8. Comparison of demographic characteristics of attenders and non-attenders

Characteristic	Attenders N=585 (53%)	Non-attenders 510 (47%)	P value*
Age group %			0.38
45-49	50.6	49.4	
50-54	54.5	45.5	
55-59	54.1	45.9	
60-64	52.2	47.8	
65-69	62.3	37.7	
Women %	57.2	42.8	0.01
Men %	49.3	50.7	
Married/living as married %	53.8	46.2	0.89
All other %	52.4	47.6	
Ethnicity			
White %	54.1	45.9	0.14
Non-white %	46.7	53.3	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.9. Comparison of socio-economic characteristics of attenders and non-attenders

Characteristic	Attenders N=585(53%)	Non-attenders N =510 (47%)	P value*
Education %			0.84
Higher qual.	61.7	38.3	
A level	55.6	44.4	
O level	60.0	40.0	
Other	54.2	45.8	
None	50.8	49.2	
Employment status			
Full/Part time %	52.7	47.3	0.4
All other %	55.6	44.4	
Car ownership			
Yes	54.6	45.4	0.09
No	44.2	55.8	
Home ownership			0.01
Owned/mortgaged %	55.7	44.3	
All other %	44.6	55.4	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.10. Comparison of health measures of attenders and non-attenders

Characteristic	Attenders N=585 (53%)	Non-attenders N =510 (47%)	P value*
Physical health			0.8
Permanently sick/disabled %	48.3	51.7	
Long standing illness %	54.2	45.8	
No physical limitations %	53.3	46.7	
General health			0.02
Bad %	46.7	53.3	
Fair %	49.5	50.5	
Good %	55.7	44.3	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.11. Comparison of health behaviour/psychological characteristics of attenders and non-attenders

Characteristic	Attenders N=585(53%)	Non-attenders N =510 (47%)	P value*
Smoker %	48.9	51.1	0.19
Non-smoker %	55.0	45.0	
Energy expenditure † kcals/kg/week (mean)	9.5	8.3	0.11
No occasions of moderate or vigorous physical activity %	47.0	53.0	0.14
≥1 occasion of moderate or vigorous physical activity %	54.2	45.8	
Alcohol units/week (mean)	6.0	7.9	0.01
Readiness to change %			0.36
Low = 1	47.9	52.1	
2	49.7	50.3	
3	46.2	53.8	
4	59.6	40.4	
High = 5	62.4	37.6	

*P values are χ^2 for trend , χ^2 or t-test as appropriate. † Sum of moderate and vigorous intensity physical activity.

Logistic regression procedures were used to calculate odds ratios for attendance. The dependent variable was attendance or not and the independent variables included all baseline characteristics shown in tables 7.3-7.6. After adjustment for all other baseline characteristics the significant independent predictors of attendance were readiness to take up regular physical activity and alcohol intake. Although there was no significant trend between quintiles of readiness to change and attendance (Table 7.11), compared to the least ready subjects, the most ready subjects were 1.74 times more likely to attend (Table 7.12). Each unit of alcohol consumed per week reduced to the likelihood of attending by 2% (Table 7.12).

Table 7.12. Adjusted* odds ratios (95% CI) for attending

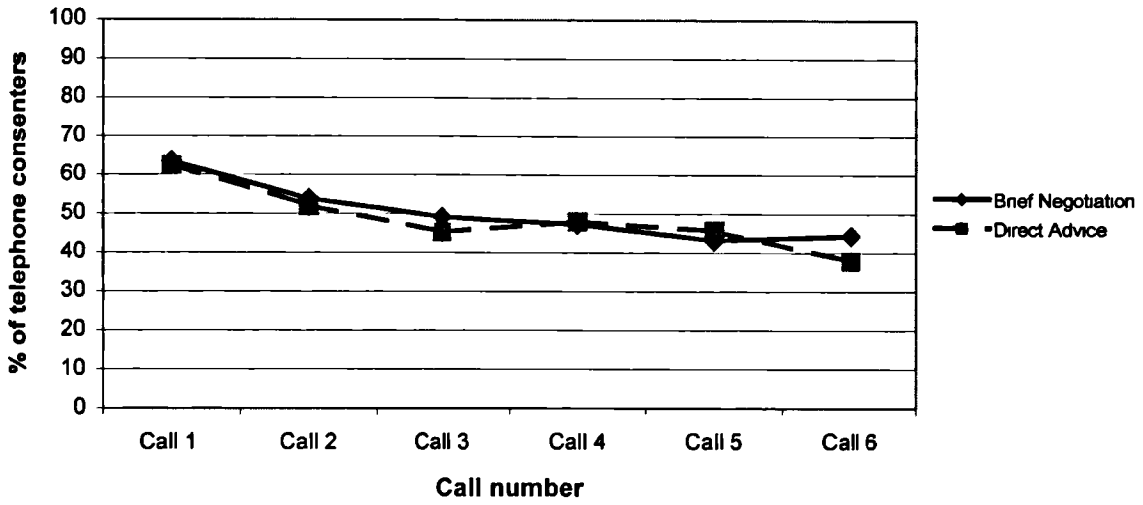
Characteristic	OR	95% CI	P value
Readiness to change			0.01
Low = 1	1		
2	0.99	(0.64 – 1.54)	
3	0.9	(0.57 – 1.43)	
4	1.52	(1.01 – 2.30)	
High = 5	1.74	(1.13 – 2.69)	
Units of alcohol per week	0.98	(0.97 – 1.00)	0.01

*Adjusted for all other baseline characteristics

7.2 TELEPHONE FOLLOW UP

The success rate of each of the 6 telephone calls is shown in Figure 7.2. The proportion of successful calls reduced from just over 60% for the first call to 40% for the last call. The mean number of successful calls was 3 for each group with the mean duration of all 6 calls 7.6 minutes in the brief negotiation group and 7.0 minutes in the direct advice group. The reduction in number of successful calls reflects the reduction in hours worked by Charlie Foster as the study progressed. His reduction in working hours reduced the amount of time available to make calls, particularly in the evenings.

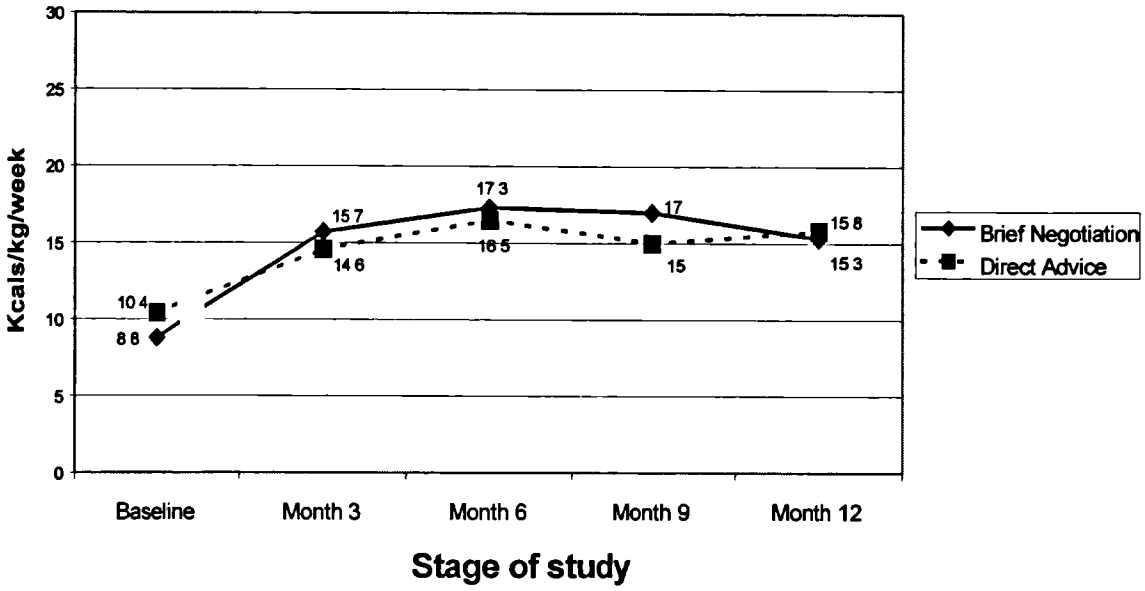
Figure 7.2. Success rate of telephone follow up by intervention group in telephone consenters (n=530)



7.3 PHYSICAL ACTIVITY LEVELS AT BASELINE 3, 6, 9 AND 12 MONTHS

Figure 7.3 shows physical activity levels, reported as kcals/kg/week, at baseline, 3, 6, 9 and 12 months by intervention group for study consenters. The broken parallel lines between baseline and 3 months represent the different methods used to measure physical activity; 4 week recall at baseline and physical activity log books at 3, 6, 9 and 12 months. Subjects at each interval who failed to return a log book were assumed not to have changed and were assigned their baseline value. The imputation model based on reported activity in the control subjects could not be used in this analysis as only intervention subjects provided intermediate log books. As a result there is a lower estimate of mean energy expenditure at 12 months compared to that reported later in the main outcomes. After the initial increase in activity between baseline and 3 months, energy expenditure was stable in both groups. Unadjusted comparisons between groups at each interval revealed no significant differences ($p>0.05$).

Figure 7.3. Mean kcals/kg per week at baseline, 3, 6, 9 and 12 months (BOCF*) by intervention arm in study consenters (n=585)



*Baseline observation carried forward

7.4 CHANGES IN PHYSICAL ACTIVITY

Both the control group and the combined intervention group showed significant increases in physical activity over baseline with no between group difference (Table 7.13). Energy expenditure increased 124% over baseline in the intervention subjects which is equivalent to approximately 166 minutes of brisk walking per week for a person weighing 70kgs. In control subjects the percentage change is approximately equivalent to an extra 154 minutes of brisk walking per week. These estimates of duration would vary depending on the actual activity being undertaken and the persons actual bodyweight. More vigorous activities than brisk walking would translate into shorter durations and heavier subjects would expend more energy for the same activity than lighter subjects.

Table 7.13. Mean percent changes in physical activity at 12 month follow up in all randomised subjects

Measure	Intervention n=(1095) Mean change % (95% CI)	Control n=(561) Mean change % (95% CI)	Between group difference % (95% CI)*	P value
Energy expenditure kcals/kg per week	124 (110 to 137)	113 (95 to 133)	3.7 (-4.7 to 12.5)	0.39

*Change in weekly energy expenditure, expressed as a percentage of energy expenditure at 12 month follow up, and adjusted for baseline energy expenditure, age, gender, health status, employment, education and home ownership.

Changes in physical activity, body mass index and blood pressure comparing the two intervention groups who consented are shown in Table 7.14. Energy expenditure increased over baseline in both intervention groups but there was no significant between group difference. The change in energy expenditure in brief negotiation subjects is approximately equivalent to an increase of 193 minutes per week of brisk walking and 170 minutes in direct advice subjects (assuming a bodyweight of 70kgs).

Body Mass Index was virtually unchanged in both groups. Systolic blood pressure reduced in both groups but there was no between group difference. Diastolic blood pressure reduced in brief negotiation subjects but not direct advice and the between group difference was significant ($p<0.01$).

Table 7.14. Mean changes in physical activity, Body Mass Index (BMI) and blood pressure at 12 month follow up by intervention received

Measure	Brief Negotiation n=(302) Mean change (95% CI)	Direct Advice n=(285) Mean change (95% CI)	Between group difference (95% CI)	P value
Energy expenditure kcals/kg per week %	148 (117 to 183)	98 (75 to 125)	10.2 (-3.9 to 26.1)*	0.16
Body Mass Index	0.0 (-0.2 to 0.2)	0.01 (-0.2 to 0.2)	-0.03 (-0.36 to 0.30) §	0.86
Systolic BP, mmHg	-3.2 (-4.6 to -1.7)	-2.9 (-4.4 to -1.4)	-0.3 (-2.5 to 1.9) †	0.81
Diastolic BP, mmHg	-2.5 (-3.5 to -1.5)	-0.2 (-1.2 to 0.7)	-2.3 (-3.8 to -0.8) ‡	<0.01

*Change in weekly energy expenditure, expressed as a percentage of energy expenditure at 12 month follow up, and adjusted for baseline energy expenditure, age, gender, health status, employment, education and home ownership.; § adjusted for baseline BMI (weight in kgs/height^2 in metres), age and energy expenditure; † adjusted for baseline weight, blood pressure, smoking, home ownership and age; ‡ adjusted for baseline blood pressure.

Comparisons between the two intervention groups and the control group, considering only those subjects who provided complete follow up data, show that, as before, all groups significantly increased over baseline. However, unlike the previous analysis brief negotiation subjects changed significantly more than controls whereas direct advice subjects did not (Table 7.15). The net difference in physical activity between control and brief negotiation subjects is equivalent to 173 kcals/week for a 70kg person. This is roughly equivalent to 37 minutes of brisk walking per week.

Table 7.15. Mean changes in physical activity at 12 month follow up by randomisation in study completers

Measure	Brief Negotiation n=(177) Mean change % (95% CI)	Direct Advice n=(178) Mean change % (95% CI)	Control n=(319) Mean change % (95% CI)
Energy expenditure kcals/kg per week %	142 (101 to 191)	82 (55 to 114)	109 (84 to 137)
Difference between intervention group and control*	24 (7 to 44)	4 (-12 to 21)	
P value for difference between intervention group and control	<0.01	0.61	

*Change in weekly energy expenditure, expressed as a percentage of energy expenditure at 12 month follow up, and adjusted for baseline energy expenditure, age, gender, health status, employment, education and home ownership.

7.5 EFFECT OF BASELINE PHYSICAL ACTIVITY ON 12 MONTH CHANGES

Table 7.16 shows differences in changes in physical activity between intervention and control subjects for three different categories of baseline energy expenditure. The three different levels of energy expenditure represent levels of physical activity often used to classify populations as sedentary (<7 kcals/kg/week) occasionally active (7 -14 kcals/kg/week) and meeting current recommendations (> 14 kcals/kg/week). It is clear that subjects classified as sedentary at baseline change the most with no significant difference between intervention and control subjects. This might be expected as this group are doing so little physical activity that the scope for change is great. There is a marked reduction in changes in the occasionally active group compared to the sedentary group. It is quite possible that this group of subjects already regard themselves to be active enough and so motivation to change may be low. Again there was no significant difference between intervention and control groups at this level of physical activity. Subjects already active at recommended levels show a small decline in physical activity over the 12 months of the study, although the confidence intervals include zero. These results suggest that those who were physically active at baseline were able to maintain it over 12 months. The intervention had no significant effect on physical activity above that of controls.

Table 7.16. Mean percent changes in physical activity at 12 month follow up in all randomised subjects by baseline physical activity

Measure	Intervention n=(1095) Mean change % (95% CI)	Control n=(561) Mean change % (95% CI)	Between group difference % (95% CI)*	P value
< 7 kcals/kg per week at baseline				
Energy expenditure kcals/kg per week	481 (431 to 536)	381 (322 to 447)	5.57 (-9.42 to 20.9)	0.45
7- 14 kcals kg per week at baseline				
Energy expenditure kcals/kg per week	86 (75 to 99)	86 (67 to 105)	1.6 (-17.4 to 20.9)	0.87
> 14 kcals/kg per week at baseline				
Energy expenditure kcals/kg per week	-1 (-7 to 3)	-2 (-15 to 5)	4.5 (-9.42 to 18.5)	0.50

*Change in weekly energy expenditure, expressed as a percentage of energy expenditure at 12 month follow up, and adjusted for baseline energy expenditure, age, gender, health status, employment, education and home ownership.

The same analysis was carried out on the two intervention arms of the study, that is those subjects who actually received either one of the interventions (Table 7.17). Patterns of change are similar to those observed in Table 7.14 with the least active subjects at baseline changing the most. Changes over baseline in the least active group were greater than those seen in the analysis of all randomised subjects. No significant differences were observed between the two intervention groups for any of the three levels of baseline physical activity.

Table 7.17. Mean percent changes in physical activity at 12 month follow up by intervention group and baseline physical activity

Measure	Brief Negotiation n=(302) Mean change % (95% CI)	Direct Advice n=(285) Mean change % (95% CI)	Between group difference % (95% CI)*	P value
< 7 kcals/kg per week at baseline Energy expenditure kcals/kg per week	582 (464 to 725)	426 (331 to 536)	14.3 (-12.7 to 46.2)	0.30
7 -14 kcals/kg per week at baseline Energy expenditure kcals/kg per week	99 (68 to 139)	77 (49 to 108)	19.7 (-16.2 to 66.5)	0.28
> 14 kcals/kg per week at baseline Energy expenditure kcals/kg per week	5 (-8 to 19)	-2 (-14 to 11)	6.99 (-13.9 to 31.0)	0.50

*Change in weekly energy expenditure, expressed as a percentage of energy expenditure at 12 month follow up, and adjusted for baseline energy expenditure, age, gender, health status, employment, education and home ownership.

7.6 EFFECT OF BASELINE CHARACTERISTICS ON STUDY COMPLETION

Differences in study completion rates in consenting, intervention subjects by baseline characteristics are shown in Tables 7.18-7.21. Univariate analysis shows that study completers were older, car and home owners, in good physical health, not completely sedentary and not ready to take up regular physical activity.

Table 7.18. Comparison of demographic characteristics of study completers and non-completers

Characteristic	Completers N=355 (61%)	Non-completers 230 (39%)	P value*
Age group %			0.03
45-49	54.8	45.2	
50-54	58.3	41.7	
55-59	62.4	37.6	
60-64	66.9	33.1	
65-69	66.7	33.3	
Women %	60.2	39.8	0.78
Men %	61.3	38.7	
Married/living as married %	60.4	39.6	0.85
All other %	62.4	37.6	
Ethnicity			
White %	61.6	38.4	0.15
Non-white %	51.0	49.0	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.19. Comparison of socio-economic characteristics of study completers and non-completers

Characteristic	Completers N=355 (61%)	Non-completers 230 (39%)	P value*
Education %			0.20
Higher qual.	70.3	29.7	
A level	72.0	28.0	
O level	67.9	32.1	
Other	53.1	46.9	
None	58.7	41.3	
Employment status			
Full/Part time %	60.7	39.3	0.99
All other %	60.6	39.4	
Car ownership			
Yes	62.5	37.5	0.02
No	43.4	56.6	
Home ownership			0.03
Owned/mortgaged %	63.0	37.0	
All other %	48.3	51.7	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.20. Comparison of health measures of study completers and non-completers

Characteristic	Completers N=355 (61%)	Non-completers 230 (39%)	P value*
Physical health			0.04
Permanently sick/disabled %	34.5	65.5	
Long standing illness %	67.3	32.7	
No physical limitations %	59.4	40.6	
General health			0.39
Bad %	35.7	64.3	
Fair %	62.0	38.0	
Good %	61.1	38.9	

*P values are χ^2 for trend , χ^2 or t-test as appropriate.

Table 7.21. Comparison of health behaviour/psychological characteristics of study completers and non-completers

Characteristic	Completers N=355 (61%)	Non-completers 230 (39%)	P value*
Smoker %	53.1	46.9	0.07
Non-smoker %	63.2	36.8	
Energy expenditure † kcals/kg/week (mean)	11.1	7.5	0.001
No occasions of moderate or vigorous physical activity %	32.7	67.3	<0.001
≥1 occasion of moderate or vigorous physical activity %	63.6	36.4	
Alcohol units/week (mean)	6.3	5.6	0.43
Readiness to change %			0.003
Low = 1	69.1	30.9	
2	67.1	32.9	
3	63.9	36.1	
4	57.7	42.3	
High = 5	63.1	36.9	

*P values are χ^2 for trend , χ^2 or t-test as appropriate. † Sum of moderate and vigorous intensity physical activity.

Stepwise logistic regression procedures were used to calculate odds ratios for study completion. The dependent variable was completion or not and the independent variables included all baseline characteristics shown in tables 7.3-7.6. After adjustment for baseline characteristics the significant independent predictors of study completion were permanent

sickness or disability and no moderate or vigorous intensity physical activity at baseline (Table 7.22). Disabled or permanently sick subjects were 60% less likely to complete the study compared with subjects who reported no physical limitations. Compared to subjects doing any moderate or vigorous intensity physical activity, subjects doing no physical activity of this intensity were 71% less likely to complete the study.

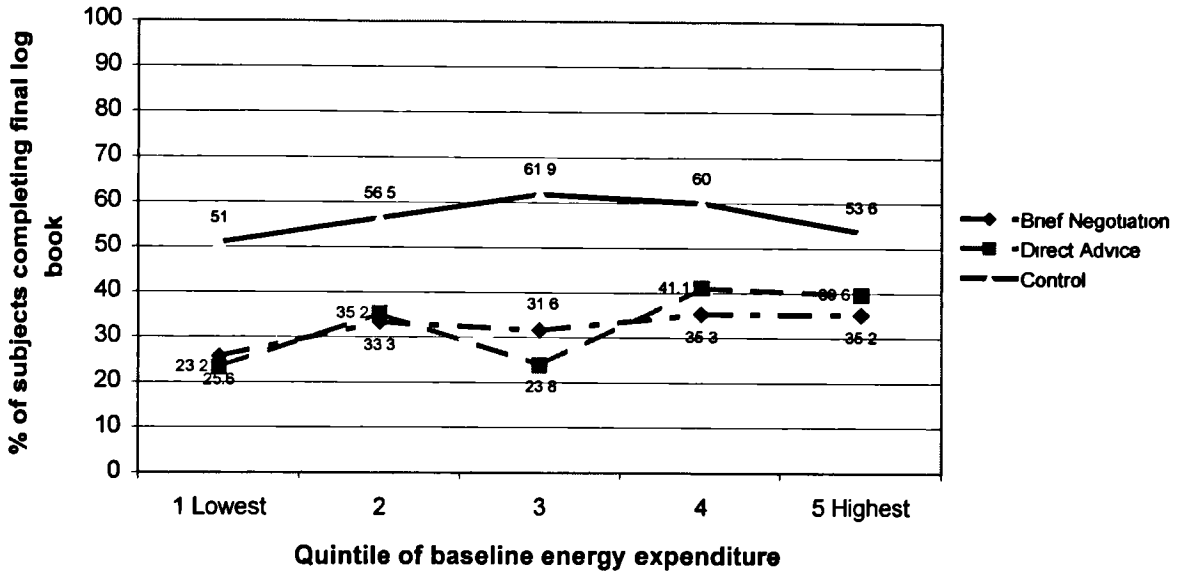
Table 7.22. Adjusted* odds ratios (95% CI) for intervention subjects completing the study

Characteristic	OR	95% CI	P value
No physical limitations	1		
Long standing illness	1.4	(0.97 – 2.04)	0.07
Permanently sick or disabled	0.40	(0.18 – 0.89)	0.03
≥1 occasion of moderate or vigorous physical activity	1		
No occasions of moderate or vigorous physical activity	0.29	(0.16 - 0.53)	<0.001

*Adjusted for all other baseline characteristics

Figure 7.4 shows the rate of study completion (returning the final log book) by quintile of baseline energy expenditure for all randomised subjects. It can be seen that in the two intervention groups, a higher proportion of the most active subjects provided final data compared to the least active, 40% vs 26% in the direct advice group and 35% vs 23% in the brief negotiation group. Control subjects show less variation and very little difference between the bottom and top quintiles. It is therefore possible that the effect of the intervention is underestimated in Table 7.17 as those subjects who were most active at baseline were least likely to change.

Figure 7.4. Completion rate by quintile of baseline energy expenditure all randomised subjects



Chapter 8 Quality Control

8.1 VALIDATION OF LOG BOOKS

As described in Chapter 6, Section 6.9, a purposive sample of 56 subjects who attended the follow up health check were asked to wear Tritrac accelerometers (Hemokinetics, Madison, WI) to provide some corroboration of their self-reported physical activity. Initially, I attempted to recruit a random sample of subjects for this exercise using a random number table. However, due to non attendance, many of the accelerometers that were initialised were not collected. This was wasting a lot of time because of the need to reinitialise them for each new subject. Therefore, each Tritrac device was initialised by CF on the morning of issue for all subjects due in on that morning. If subjects failed to attend, the devices were reinitialised during a lunch break for subjects due to attend in the afternoon and early evening. The accelerometers were initialised via a computer interface, with the subjects height, weight and gender. The measurement intervals were set at 5 minutes as earlier pilot work had revealed that when the intervals were set to 1 minute the battery life expired prior to one week, losing all the data collected.

Subjects were asked to wear the accelerometers for the first 7 days that they were recording activities in the 28 day log book, and to commence both of these activities the day after attending for the health check. They were asked to wear the device around their waist during waking hours with a Velcro fastening belt that was provided. They were then requested to return the devices to the medical centre after 7 days. Subjects were told that the devices measured the general moving about that they did, that would not be recorded in the log books.

Nobody who was asked to wear the devices refused. I checked to ensure that each subject had completed a log book. Forty subjects provided both TriTrac and self-reported data. Of the 40 subjects providing two measures, 12 were from the brief negotiation group, 15 were from the direct advice group, 13 were from the control group and 60% were female. Compared to those wearing TriTrac devices, the other 634 study completers expending on average 12 kcals/kg/week less (95% CI, -24 to -7; p=0.04).

The data collected from each device was uploaded onto a computer and saved in an Excel spreadsheet. Energy expenditure, in kilocalories, was provided in 5 minute blocks (kcals/5min) by time of day. For each subject, the actual calories computed per day were summed. Actual calories are the calories expended above basal metabolic rate and therefore represent some movement. A number of subjects started their data collection on the day they collected the device and finished it on the day they returned it. This meant that only days 2-6 included a complete 24 hours. For this reason the comparisons between the Tritrac data and the self-reported data were made for days 2-6 only.

The daily energy expenditure for each of the 5 TriTrac days were summed for each subject. Energy expenditure, in kilocalories, was calculated for each of the log book days 2-6 for subjects providing TriTrac data. The energy cost of each of the activities in the log book was calculated using the formula duration (mins) / 60 x METs x bodyweight (Kg). All activities were then summed to produce kilocalories per day.

To compare the extent of the agreement between the two measurement methods, the mean energy expenditure from the total of the 5 days was calculated for each measure. The

agreement between the two measures was assessed using the method described by Bland and Altman (1986).

The distribution of the 5-day energy expenditure values were skewed. Therefore, both measures were transformed which improved the Normality of the distribution.

Table 8.1 Five day energy expenditure by measure (Logged kcals)

Measure	N	Minimum	Maximum	Mean	Std. Deviation
Log log book	40	5.2	9.6	7.6	1.2
Log TriTrac	40	5.2	8.5	7.5	0.7

The mean energy expenditure assessed by the log book was higher than TriTrac by 94 kcals and had greater variability (Table 8.1). The differences between the two measures on the log scale show that they are approximately normally distributed and include positive as well as negative differences (Figure 8.1). The differences are correlated with the average of the measures ($r=0.54$) and are significant ($p<0.001$), suggesting systematic bias. Figure 8.2 shows that differences are greatest for the most active and the least active. For the highest average energy expenditures log book values are greater than TriTrac and for the lowest average energy expenditure TriTrac values are greater than log book. As neither of these measures is regarded as a the gold standard it is not possible to say which of them represents the truth. Importantly, the mean differences were not significantly different between randomised groups ($p=0.6$).

Figure 8.1. Differences in energy expenditure between self-report and TriTrac.

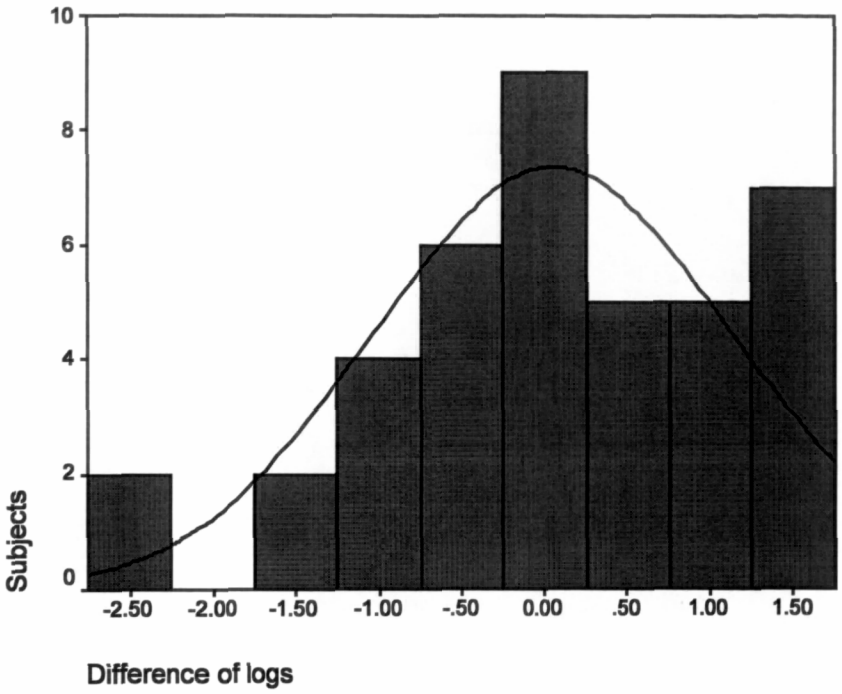
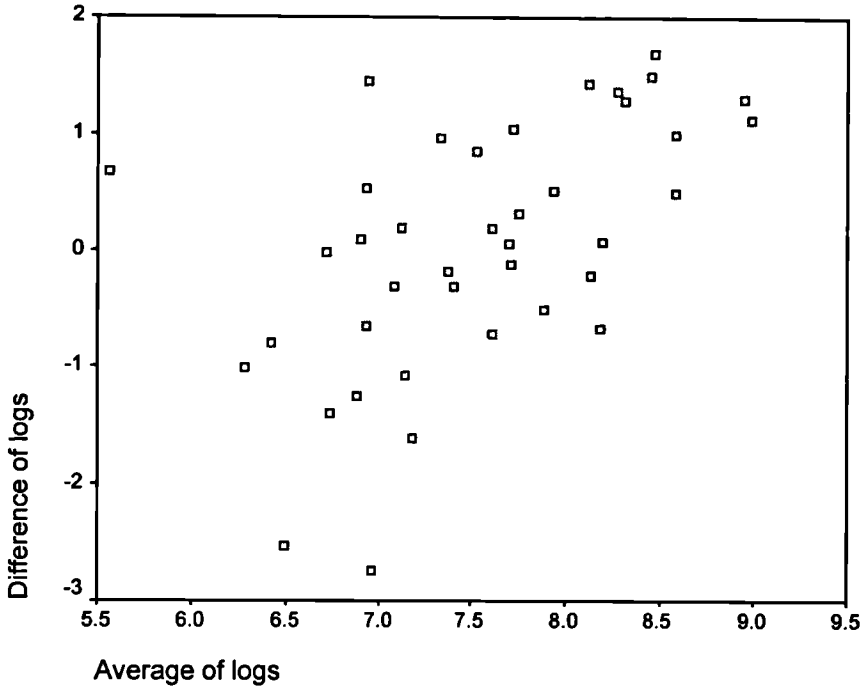


Figure 8.2 Comparison of the average and differences in energy expenditure between self-report and TriTrac



Others have found similar results and have suggested that, compared to log book data, TriTrac overestimates time spent in sedentary behaviours and underestimates time spent in active behaviours (Matthews & Freedson, 1995).

Although there are systematic differences between the two measures, they are correlated (r=0.4). This means that we cannot say how valid self-reported physical activity is, but we can be confident in distinguishing between active and sedentary subjects.

8.2 ADHERENCE TO INTERVENTION PROTOCOL

To assess the extent to which the two intervention protocols were adhered to, all interventions were audio taped with participants' permission.

A random sample of 30 tapes were selected for analysis using a random number table. They were listened to by myself and Daran Woodward, who was not involved in the study but who is familiar with exercise interventions. We were blind to each person's randomisation. The tapes were wound forward to approximately half way and listened to until the listener felt able to state which treatment group the subject was in. At this point each of us recorded a '1' for Brief Negotiation and a '2' for Direct Advice.

The two sets of scores were entered into an SPSS database and assessed for inter-rater agreement using the Kappa-statistic. There was 100% agreement between us giving a Kappa score of 1. I then made a final check, comparing our group assignment to the actual randomised groups, which revealed that 14 were from the brief negotiation group and 16 were from the direct advice group. We accurately assigned all participants to the correct intervention group.

Chapter 9 Discussion

9.1 INTRODUCTION

This study compared the effectiveness of brief negotiation to direct advice and to a no-intervention control group in promoting the adoption of physical activity in an insufficiently active population of middle aged men and women. There are a number of strengths of this trial that add to our understanding of physical activity promotion.

9.2 STRENGTHS AND WEAKNESSES

Targeting middle aged men and women who were not meeting current public health recommendations for physical activity, via direct mail, led to the recruitment of a group of study participants who, it has been estimated, stand to gain the most from increased physical activity (Pate et al, 1995; Naidoo et al, 1997). Twenty eight per cent of all registered patients in the target group were randomised. Although it is not possible to make direct comparisons with other studies, due to differences in the study populations and exclusion criteria, the proportion of randomised people is high compared to a similar trial which randomised 17% of registered patients in the target group (Harland et al, 1999).

Randomising participants after stringent inclusion criteria, and after they have attended for screening, can result in recruiting a highly selected group of motivated participants. This can threaten the external validity of a trial and lead to exaggerated results (Davey Smith & Ebrahim, 1999). I attempted to avoid this selection bias by randomising participants at the point of invitation, rather than after they had accepted an invitation to attend an appointment with a health/fitness professional. In the event, the measure of

readiness/motivation to take up regular physical activity used in this study showed no difference between those who were randomised and those who were not (Table 7.6).

Although we attempted to minimise any selection bias, the process of inclusion and randomisation inevitably leads to differences between those randomised and those who are not. Randomised participants were more likely to be men, without formal qualifications, in part-time or full time employment, in fair health without physical limitations and smokers. These differences are mainly consistent with the inclusion criteria of being insufficiently active. The participants lost through the recruitment process were mainly those who did not return the baseline questionnaire, those who were already active and those with poor physical health.

A major strength of this trial was the inclusion of a no intervention control group. By using a Zelen, single consent, randomized design, control participants received no intervention at all, including no exposure to study staff at baseline for measuring purposes.

The 585 participants who received an intervention represents 53% of those invited and 10% of all registered patients in the 45-64 age group. Ten percent of all registered patients is a much higher recruitment rate than other primary care physical activity interventions in England, which have been estimated to recruit less than 1% of all registered patients (Fox et al, 1997). This stage of the recruitment process revealed that those most ready to change their physical activity were 1.74 times more likely to attend than those who were least ready (Table 7.12). This was unexpected given that subjects were not invited to an exercise intervention but a routine health check. It is possible that

those willing to accept the offer of a health check are generally more ready to change their lifestyle.

The interventions in this study were grounded in theories of health behaviour change and were delivered in a naturalistic setting. They were delivered with minimal disruption to usual practice and were well received by members of the primary care team.

It is often difficult in health promotion trials to achieve single or double blinding. In this trial, participants were blind to the treatment, although the practitioner was not. It was possible to blind participants because the difference between treatments was an interpersonal style which would probably only be detectable by a trained observer. This hopefully reduced the number of people who refused consent. Refusal to be randomised can be a problem if participants have a strong preference for one treatment over another. This has been a problem with a trial which randomised people to a health club or a physical activity discussion group. As might be expected participants were keen to be randomised to the health club (Dunn 1998, personal communication). Strong patient preferences can affect the internal validity of a trial if those receiving the intervention they want are more motivated to adhere to the intervention and vice versa. In the case of the Move-It Trial, participants consented to a study which they were told was testing the effect of two different styles of health professional communication on health behaviour. They knew that by accepting randomisation they would not know which group they were in. With only subtle, albeit significant, differences in interventions, it is unlikely that participants would have had any insight into to the intervention they were receiving, thus they were blind to it. Prior to consent, the practitioner in this trial was blind to the randomisation and because randomisation took place before consent they could not interfere with it. Even if the practitioner had been motivated enough to deliver the

treatment they thought more appropriate for a subject, instead of the one they were randomised to, this would have been revealed in the audio tape of the consultation. As discussed below, no such deviation from the protocol was detected.

The fact that just one practitioner delivered both interventions is both a strength and a weakness. It eliminates the risk of therapist effect, which could undermine internal validity if present, but limits the extent we can generalise the findings to other members of the primary care team.

A trial that compared contrasting interpersonal styles for reducing alcohol intake suggested that the lack of an effect may have been due to deviation from the study protocol, leading to only small differences between interventions (Bell & Rollnick, 1992). The interventions in this trial followed a written protocol and were audio taped. Two reviewers, blind to randomisation, were both able to accurately assign participants to the correct group for all 30 of the randomly selected tapes with 100% agreement between the reviewers. This would suggest that there was a genuine difference between the treatment arms and that the protocol for each intervention was adhered to.

The main limitation of this trial was the larger than expected loss to follow up, reducing statistical power. This has been reported as a down side of the Zelen design which allows for participants to exit from the study, by refusing consent, after randomisation (Jadad, 1998). Obviously, if randomisation takes place after consent, then the risk of withdrawal is lower.

Another important limitation of this trial is the reliance on self-reported physical activity. While we attempted to corroborate self-reported physical activity with electronic motion

sensors and could show that the methods were correlated, they both have inherent error and therefore proper validation of self-report was very difficult to achieve. Even those self-report measures that have been validated (Chapter 5) were mainly done for prevalence or cohort studies. When applied in intervention studies a different range of factors, including the Hawthorn effect, may influence subject responses. It is hoped that any reporting bias that existed was not selectively different between groups.

As mentioned in the methodology section (Chapter 5) a threat to the external validity of trials is the use of highly skilled personnel delivering specialist treatments which are unlikely to be replicated in normal practice. In this trial CF had received more training in the brief negotiation intervention than might be expected of a GP or practice nurse. However, the brief negotiation intervention was designed with primary care staff in mind and was intended to require no more than 12-15 hours of training. Both interventions lasted 30 minutes, much longer than a GP could commit to, but possible for a nurse. If the research elements of the trial were removed the intervention time would probably be closer to 20 minutes. The aim of this trial was to determine if any intervention is better than none and whether one intervention was better than the other. It was not attempting to measure whether primary care staff could be trained in the intervention methods. If a trial of this nature showed either of the interventions to be worthwhile, then it would be appropriate to carry out further research on effective dissemination of the method.

9.3 FINDINGS OF THE TRIAL IN RELATION TO EXISTING LITERATURE

Intention to treat analysis of the two intervention groups versus the control group showed no significant between group differences in changes in physical activity. Both intervention and control groups showed significant increases in physical activity over

baseline repeating the changes observed in control participants by Bull et al (1998). This worst case scenario, which included all those invited to the intervention, including those who failed to attend, is arguably a measure of the effectiveness of the combined interventions if applied to everyday practice. The efficacy of the interventions is underestimated as 47% of intervention participants were not exposed to either of the interventions.

The intention to treat analysis of brief negotiation versus direct advice in those participants who attended, revealed that the brief negotiation group showed a mean change in their physical activity 10% greater than that of the control group, which is approximately equivalent to 23 minutes of moderate intensity physical activity per week. However, the difference was not statistically significant and therefore could have occurred by chance. As with the first analysis, both groups significantly increased their physical activity over baseline by 148% and 98% in the brief negotiation and advice groups respectively.

Of the participants who received either of the interventions and who provided a record of their physical activity 12 months later, those who received 30 minutes of brief negotiation increased their physical activity significantly more than controls, whereas those who received 30 minutes of direct advice did not. Although this 'treatment received' analysis is open to selection bias, in that it would be expected that study completers would have changed more than those who failed to complete the study, this does not explain why one intervention is significantly better than nothing and one is not. Comparisons of intervention participants who completed the study and those who did not showed that the only significant independent predictors of completion were doing at least 1 occasion of

moderate or vigorous intensity physical activity per month at baseline and not being permanently sick or disabled. Interestingly, although not quite reaching significance, participants who reported some long standing illness but who were not permanently sick at baseline, were 40% more likely to complete the study compared to those in good physical health. Those permanently sick or disabled were 60% less likely to complete the study. It might be argued that these participants should not have been recruited. However, this item was taken from their question in the baseline questionnaire about work status. If when they attended the health check it was clear they were able to walk, then they stayed in the study. Participants who were not undertaking at least one period of moderate or vigorous intensity physical activity at baseline were 70% less likely to complete the study. Another study has shown that the completely sedentary adhere less well to a physical activity intervention compared to those who are underactive (Young et al, 1995).

The percentage change in physical activity at 12 months was related to baseline physical activity. The most sedentary group at baseline, those expending less than 7 kcals/kg/week, increased their physical activity over baseline by 481% in the combined intervention group and 381% in the control group. This compares to a small non significant reduction in physical activity, over 12 months in those already active (> 14 kcals/kg/week) at baseline. Although these changes were large there was no significant between group differences.

Blood pressure was only measured in the two intervention groups. Both groups reduced their systolic blood pressure at 12 months, by 3.2 mmHg in the brief negotiation group and 2.9 mmHg in the direct advice group, but there were no significant between group differences. Only the brief negotiation group showed a significant reduction in diastolic

blood pressure (-2.5 mmHg) at 12 months, significantly different from the direct advice group. There is no obvious explanation for the significant difference between the intervention groups for diastolic blood pressure but not systolic blood pressure. Neither intervention group showed any change in body mass index at the 12 month follow up.

The failure of this study to demonstrate significant changes in physical activity for either of the intervention groups, above those seen in the control group, is disappointing. The increases in energy expenditure in intervention are consistent with what was expected and with the size of changes observed in other trials with walking as the target behaviour (Chen et al, 1998). However, the significant increase in energy expenditure over baseline seen in the control participants was not expected. It appears that this larger than expected change in the control group prevented any significant between group differences. This observation is not unique to this study, having been observed in two other primary care studies which included no- intervention control groups. In the Harland et al (1998) study, 23% of control participants increased their physical activity over baseline after 1 year and in the Stevens et al (1998) study 13% did. In an Australian study of a brief primary care based intervention, 31% of control participants were classified as 'now active' at 1 year follow up (Bull et al, 1998). Only the study by Stevens et al (1998) showed any significant between group differences in change in physical activity.

There are a number of possible explanations for the increased physical activity in the control group. One explanation is that although the control group was not exposed to any kind of intervention in this trial, they were asked to keep a 28 day diary which may have produced some kind of Hawthorn effect. It is possible that the data from the follow up physical activity diary was influenced by a desire to 'please' CF resulting in an over

reporting bias in all groups. However, this does not explain the differential changes in energy expenditure seen in the treatment received analysis.

Another possible explanation is that changes in energy expenditure are a result of regression to the mean. Although it has been proposed that sedentary participants not exposed to an intervention would get more sedentary over time (Dunn et al, 1999), we did not find this. Baseline physical activity was independently, inversely related to changes physical activity at 12 months. In other words, being sedentary at baseline was the best predictor of change in physical activity at follow up, independent of randomised group. Also, results from a 12 month follow up survey of 3,451 adults aged 16-74,interviewed in 1996 and 1997 showed that 38% of sedentary men and 44% of sedentary women had increased their physical activity during this period (Dodd, 1998).

During the period of this trial the Health Education Authority were undertaking the Active for Life Campaign, with its central focus a national mass media campaign aimed at promoting regular, moderate intensity physical activity. Although results of the evaluation of this campaign are not yet available, there is a small chance that the campaign produced the changes seen in control participants. It is not unreasonable to speculate that the first two explanations combined offer the best explanation of the control group changes.

The lack of a statistically significant difference between the brief negotiation and the direct advice group is mainly explained by the large loss to follow up. We required 400 participants in each group to detect a 5 kcal/kg/week difference between groups, but only managed to recruit 585 participants in total. This obviously reduced our power

substantially. In addition, the observed difference between the groups was less than the predicted 5 kcals/kg/week, being closer to 3 kcals/kg/week.

Differences in interventions, populations and measures make comparisons between this trial and others limited. However, the failure of this trial to produce significant between group differences in physical activity at 12 months follow up is consistent with other primary care based, primary prevention, physical activity trials. To date, no primary care based physical activity interventions have been able to report significant changes in physical activity between intervention and control groups for follow up periods greater than 6 months (Simons-Morton et al, 1998; Eaton & Menard, 1998). A number have been able to report short term changes in physical activity, usually around 12 weeks but these changes were not sustained (Bull et al, 1998; Goldstein et al, 1999; Harland et al, 1999). All of the interventions, including this trial, were 'brief' ranging from 5 minutes advice from a doctor to 6 meetings with a health visitor over 12 weeks. Some authors have argued that the results of these trials suggest that longer and more intensive interventions may lead to more sustained changes in physical activity. However, there is no evidence to support this view and it would need to be tested in a separate study. One study which is currently underway is attempting to address whether there is a dose-response relationship between the amount of intervention received and change in physical activity (King et al, 1998).

In the USA the use of the telephone as a means of achieving on-going support for participants is popular support (King et al, 1988; Lombard et al, 1995). In this trial the scheduled 6 follow up telephone calls only led to an extra 7.6 minutes of intervention in the brief negotiation group and 7.0 minutes in the direct advice group. Although we did

not assess the content of the telephone calls, it did appear that participants were uncomfortable with being called at home. There seemed to be an urgency to get off the phone. This wasn't so much the case when participants were called at work. It is unlikely that withdrawing these calls would have any significant impact on outcomes but would save an awful lot of time and effort.

Multiple risk factor interventions, both primary and secondary prevention, seem to hold more promise than single factor interventions. A number of such trials which have had a measure of physical activity have shown small but significant changes in the intervention group compared to controls (Ashenden et al, 1997; Steptoe et al, 1999). It is possible that people attending primary care with existing health problems may be more motivated to adhere to a physical activity regime if they believed it would benefit their condition. This warrants further study.

The fact that the brief negotiation group did not lead to significantly different changes in physical activity compared to brief advice could easily lead to the conclusion that motivational interviewing, the basis for the brief negotiation group, was not effective in promoting physical activity. However, the brief negotiation protocol was a simplified version of motivational interviewing for a non-specialist setting. Although sharing the same principles, motivational interviewing was designed for specialist alcohol settings for help seeking, problem drinkers with consultation times typically 3-4 times longer than here (Miller & Rollnick, 1991). It is not possible to say what effect more frequent and longer sessions of motivational interviewing might have on exercise behaviour, but given the encouraging results in our completers analysis, it deserves further investigation.

The research focus on brief, primary care physical activity interventions has arisen from the relative success of brief smoking interventions which have consistently shown 2% quit rates (Thorogood, 1999). Physical activity interventions might have been expected to achieve similar, if not better results. However, important differences in how supportive the social and physical environment is may partly explain why brief physical activity interventions have to date been less successful.

Brief advice from a doctor to quit smoking is supported by a physical and social environment conducive to this aim. Maintaining a smoking habit is becoming increasingly difficult with fewer places to smoke, the financial cost of smoking and social disapproval. The opposite is true for physical activity. The social norm is to be sedentary, a person is unlikely to encounter disapproval for not being active and may in fact encounter some opposition to being physically active. The physical environment is flooded with labour saving devices and the popularity of the car has dramatically reduced the amount of physical activity taken for transport. In the 20 years between 1975 and 1995 the number of miles walked per year as dropped by 20% and the number of miles cycled has dropped by 11% (DETR, 1998). Rather than being supportive of a physically active lifestyle, the environment is conducive towards sedentary living and represents a significant barrier to even the most committed exerciser.

9.4 IMPLICATIONS FOR FUTURE RESEARCH

The results of the analysis of study completers and of brief negotiation versus direct advice, suggest that research into the effectiveness of brief negotiation for promoting physical activity should not be abandoned. There is a strong suggestion from these results that if the study was replicated on a larger scale, giving more power, then statistically

significant and clinically meaningful differences in physical activity in favour of brief negotiation might well be observed. Alternatively, greater power would also be achieved if a higher recruitment rate could be obtained through a different strategy than that used here. In fact, a combination of recruitment strategies is likely to be the most effective (King et al, 1994; Harland et al, 1999). Just 32% of intervention subjects completed all parts of the study. Future researchers should be aware of this for power calculations if they intend using a Zelen design. Whilst resulting in a high drop out, arguably this study design produces a much more generaliseable sample than study designs that randomise after consent.

In addition to repeating this trial on a larger scale with multiple recruitment strategies, it might also be beneficial to target high risk groups such as those with hypertension, diabetes or post myocardial infarction. It has been argued that these high risk groups may be more motivated to change their behaviour compared to lower risk groups (Ebrahim & Davey-Smith, 1997).

The results of this trial and those of Harland et al, (1999) suggest that future research should also consider whether or not more frequent sessions of brief negotiation would lead to greater changes in physical activity compared to multiple sessions of advice which may only lead to resistance and irritation from participants.

The benefits of physical activity only exist while the behaviour is maintained. Therefore, future research is required with post intervention periods of 5 years or longer to explore the effectiveness of interventions in achieving not only an increase in the adoption of physical activity but also its maintenance. This also means that appropriate means of

follow up need to be explored. Our experience is that telephone follow up may not be best for this purpose.

The lack of change in bodyweight in our two intervention groups may be interpreted as a positive result if the background trend for bodyweight is upwards. As increases in bodyweight are associated with poorer health outcomes, weight stability is desirable. We were unable to attribute a lack of change in bodyweight to the success of either of the intervention groups because we did not have a baseline measure in the control group. Future studies would benefit from addressing this.

9.5 IMPLICATIONS FOR POLICYMAKERS

In 1994 Iliffe et al, warned primary care teams against investing time and resources in prescribing exercise before evidence existed about effectiveness, suggesting that "unevaluated initiatives may be of no more value than prescribing coloured water" (Iliffe et al, 1994). Despite this warning, primary care based exercise schemes have grown rapidly without evidence of their effectiveness (Riddoch et al, 1998). Since 1994, two UK primary care based trials have been published and we now have the results of the Move-It trial. All three have adopted different approaches to tackling the problem of increasing physical activity yet none has found an effective solution. Despite the ground swell of support for these primary care based schemes, Iliffe's warning is just as relevant now as it was in 1994.

Not only should research inform policymakers about new services which have been shown to be effective but also inform them of existing services that are shown not to be effective.

Whilst not wanting to damage current enthusiasm for promoting physical activity in primary care, it is important that limited resources are allocated to programmes and interventions that have been shown to be effective. At present, it is not possible to present an argument based on evidence, that resources should be directed towards primary care, primary prevention physical activity interventions. Before we can make a strong case for redirecting resources to primary care physical activity interventions we need to answer the following outstanding questions:

1. What is the most efficient recruitment strategy for optimising the exposure of participants to our interventions?
2. Does the provider of the intervention have an effect on outcome e.g. doctor versus other health professional?
3. Are interventions more effective if targeted at high risk participants compared to those using a population approach?

9.6 OVERALL CONCLUSIONS

In light of these findings, and those of other primary care based studies, health care purchasers should be cautious of funding brief, primary care based physical activity programmes. At present, for patients already attending primary care for conditions that might benefit from a change in physical activity, it would be worthwhile delivering approximately 20 minutes of brief negotiation to increase their physical activity. It would also be better to avoid instructing them about the need to change. Until further evidence is available, it would seem to be a waste of limited resources to specifically invite patients in if the only intention is to try to intervene in their level of physical activity.

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Appendix A

Patient Information Sheet

Patient Information Sheet
Intervention Subjects

We are doing some research in collaboration with the doctors of this medical centre. We are looking into the way in which healthcare workers communicate with patients and what effect, if any, this has on their health behaviour.

If you agree to take part you will be randomly assigned to one of two groups, each one being a different communication style - you won't know which one you are in.

We will ask you to talk about your lifestyle today, and then ask you to keep a diary of particular aspects of your lifestyle on four occasions during the next year.

During the course of the year we will keep in regular contact with you via the telephone.

We will record the meeting today on a tape recorder for quality control purposes. All the information on the tape we be strictly confidential and will only be used for research purposes.

You are free to refuse to participate in the trial or withdraw from it at any stage. If you do refuse to take part or withdraw, it will in no way affect your normal care at the centre.

Patient Information Sheet
Control Subjects

We are doing some research in collaboration with the doctors of this medical centre. We are interested in people's usual activity patterns at different times of the year.

We would like to measure your height/weight and blood pressure today, and then ask you to keep a diary over the next 28 days of your usual physical activity patterns. The diary will only take about 1-2 minutes to complete each day.

You are free to refuse to participate in the study. If you do it will in no way affect your normal care at the centre.

Appendix B

Baseline Questionnaire

Text cut off in original

NFIDENTIAL

Serial Number

ALBANY HOUSE MEDICAL CENTRE - LIFESTYLE QUESTIONNAIRE

oduction

any House Medical Centre is interested in finding out more about the health and lifestyle of its patients. s questionnaire is designed to gather information about aspects of your lifestyle that may affect your th. Better information will be valuable in developing ways of helping people improve their health.

of the information you give to us will be treated with the strictest confidence. It will only be seen by r doctor and research staff. The results will be used for research, but will **not** be presented in a way ch can be associated with names and addresses. The information will not be released to any other on or agency.

ructions

questionnaire will take you APPROXIMATELY 10 MINUTES to complete. For most questions you need to put a **cross** in the box which applies to you.

se use a **pen** to fill in the questionnaire.
mple: How is your health in general?

Very good.... ☐
Good..... ☒
Fair ..... ☐
Bad ..... ☐
Very Bad ..... ☐

---

ou want to change the answer you have given, please fill in the box with the original cross in it and put her cross in the box with the new answer.
mple:

Very good.... ☐
Good..... ☒
Fair ..... ☒
Bad ..... ☐
Very Bad ..... ☐

se answer **all** the questions **unless** you see an arrow next to your answer directing you to another stion.

Section 1 - General Health

First of all some questions about your general state of health.

How is your health in general?

PLEASE PUT A CROSS IN ONE BOX

Very good.... ☐
Good..... ☐
Fair ..... ☐
Bad ..... ☐
Very Bad ..... ☐

Do you have any long-standing illness, disability or infirmity? (By long standing we mean anything that has troubled you over a period of time or that is likely to affect you over a period of time?)

PLEASE PUT A CROSS IN ONE BOX

Yes ..... ☐
No ..... ☐

If 'Yes' please write what the trouble is:

.....

Section 2 - Smoking

The following questions are about smoking.

Do you smoke cigarettes at all nowadays?
PLEASE PUT A CROSS IN ONE BOX

Yes ..... ☐→ Go to Q4
No ..... ☐→ Go to Q5

Current Smokers Only

About how many cigarettes do you smoke a day?
PLEASE WRITE IN

☐ → Go to Q8

Non-smokers only

Have you ever smoked cigarettes regularly?
PLEASE PUT A CROSS IN ONE BOX

Yes..... ☐→ Go to Q6
No..... ☐→ Go to Q8

n-smokers only

About how many cigarettes did you smoke in a day when you smoked them regularly?
PLEASE WRITE IN

☐

Non-smokers only

How long ago did you stop smoking regularly?
PLEASE PUT A CROSS IN ONE BOX

Less than 6 months ago ..... ☐
6 months but less than a year ago ..... ☐
1 year but less than 2 years ago ..... ☐
2 years but less than 5 years ago ..... ☐
5 years but less than 10 years ago .... ☐
10 years or more ..... ☐

Section 3 - Drinking

Now some questions about alcohol and drinking.

Do you ever drink alcohol nowadays, including drinks you brew at home?
PLEASE PUT A CROSS IN ONE BOX

Yes ..... ☐
Very occasionally (e.g. birthdays, Christmas) ..... ☐ → Go to Q9
No - never drink alcohol ..... ☐ → Go to Q11

During **THE LAST 4 WEEKS**, how often have you had a drink of each of the following types of alcoholic drink?

PLEASE PUT A CROSS IN ONE BOX ON EACH LINE

	Most days	3-4 times per week	1-2 times a week	1-2 times in 4 weeks	Not at all
Beer lager etc.	☐	☐	☐	☐	☐
Spirits or liqueurs (e.g. gin, whisky etc.)	☐	☐	☐	☐	☐
Sherry or martini (including port, vermouth, Cinzano, Dubonnet)	☐	☐	☐	☐	☐
Wine (including, Babycham and Champagne)	☐	☐	☐	☐	☐

For each of the alcoholic drinks you have drunk in the **LAST 4 WEEKS**, how much have you usually drunk on any day?

Beer, lager, stout, cider	☐	pints	☐	half pints
Spirits or liqueurs.....			☐	singles
Sherry or martini			☐	glasses
Wine			☐	glasses

Section 4 - Exercise and Fitness

next questions are about physical activity and exercise.

Do you regularly take exercise to improve/maintain your health and/or fitness.
PLEASE PUT A CROSS IN ONE BOX

Yes ☐
No ☐

During the **PAST FOUR WEEKS** have you taken any exercise ***in your leisure time*** (i.e. apart from the physical activity in your job and/or at home) at least once a week for as long as 30 minutes - or 2 periods adding up to 30 minutes?
PLEASE PUT A CROSS IN ONE BOX

Yes ☐ No ☐

Below is a list of gardening activities that you may have done in the **past four weeks**. For each of the activities listed please indicate:

i. The number of separate occasions you did the activity in the past four weeks (if at all).
ii. On average, how long each separate occasion lasted.
iii. On average, how hard the activity was (you may put a cross in more than one box. E.g., you may perspire and breathe hard.)

ACTIVITY	Number of occasions in last 4 weeks	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
weeding, pruning						
with a power mower						
with a hand mower						
flowers/seeds						
clearing rough ground						
ıavy gardening						

Below is a list of different pace walks you may have done in the **past four weeks**. For each of the walks listed please indicate:

i. The number of separate occasions you did that pace of walk in the past four weeks (if at all).
ii. On average, how long each walk lasted.
iii. On average, how hard the walk was (you may put a cross in more than one box. E.g., you may perspire and breathe hard.)

ACTIVITY	Number of occasions in last 4 weeks	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
at a slow pace						
at a steady average pace						
at a fairly brisk pace						
at a fast pace						
with heavy shopping						

Below is a list of DIY activities that you may have done in the **past four weeks**. For each of the activities listed please indicate:

i. The number of separate occasions you did the activity in the past four weeks (if at all).
ii. On average, how long each separate occasion lasted.
iii. On average, how hard the activity was (you may put a cross in more than one box. E.g., you may perspire and breathe hard.)

ACTIVITY	Number of occasions in last 4 weeks	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
building work						
ng						
ıusehold repairs						
hing and polishing						
ırs and maintenance						
lease specify						

Below is a list of home-making activities that you may have done in the **past four weeks**. For each of the activities listed please indicate:

i. The number of separate occasions you did the activity in the past four weeks (if at all).
ii. On average, how long each separate occasion lasted.
iii. On average, how hard the activity was (you may put a cross in more than one box. E.g., you may perspire and breathe hard.)

ACTIVITY	Number of occasions in last 4 weeks	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
ing						
heavy furniture						
leaning						
g windows						
ng						
g floors						
lease specify						

Below is a list of sports and recreational activities that you may have done in the **past four weeks**. For each of the activities listed please indicate:

i. The number of separate occasions you did the activity in the past four weeks (if at all).
ii. On average, how long each separate occasion lasted.
iii. On average, how hard the activity was (you may put a cross in more than one box. E.g., you may perspire and breathe hard.)

ACTIVITY	Number of occasions in last 4 weeks	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
s/keep fit						
raining						
ng						
/jogging						
rugby						
on						

In this question we would like to know how you feel *personally* about **TAKING UP REGULAR EXERCISE.** By regular we mean ***30 minutes of continuous exercise on at least 5 days of the week.***

Please read each of the statements below carefully, and decide whether you agree or disagree with each of them.
PLEASE PUT A CROSS IN ONE BOX ON EACH LINE

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
think about taking up regular exercise, but never seem get round to it.	☐	☐	☐	☐	☐
am not thinking about taking up regular exercise.	☐	☐	☐	☐	☐
would like to take up regular exercise, but I'm not sure ow to get started.	☐	☐	☐	☐	☐
am seriously thinking of taking up regular exercise in e near future.	☐	☐	☐	☐	☐
ometimes I think I should take up regular exercise.	☐	☐	☐	☐	☐
lo not want to take up regular exercise right now.	☐	☐	☐	☐	☐
sometimes worry about my lack of exercise.	☐	☐	☐	☐	☐
ave done regular exercise in the past, and I want to do s again soon.	☐	☐	☐	☐	☐
There is no need for me to take up regular exercise.	☐	☐	☐	☐	☐

Could you walk for one mile (e.g. from Albany Medical Centre to the train station) continuously on the flat in 15 or 20 minutes without any discomfort or pain?
PLEASE PUT A CROSS IN ONE BOX

	Yes	No	Don't Know
15 minutes without fatigue, discomfort or pain (e.g. out of breath or aching calves)	☐	☐	☐
20 minutes without fatigue, discomfort or pain (e.g. out of breath or aching calves)	☐	☐	☐

Section 5 - Food

What do you usually spread on your bread?
PLEASE PUT A CROSS IN ONE BOX

- Butter ☐
- Butter type spread (e.g., Clover, Golden Churn) ☐
- Hard margarine or block margarine (e.g., Krona, Echo) ☐
- Polyunsaturated margarine (e.g., Flora, Sunflower, Vitalite, Soya) ☐
- Other soft margarine (e.g., Summer County, Stork) ☐
- Low fat spreads (e.g., Gold, Outline, Delight) ☐
- Other ☐
- Do not use fat spread on bread ☐

How often do you eat fruit and vegetables (fresh and/or frozen and/or tinned)?
PLEASE PUT A CROSS IN ONE BOX

More than once every day	Once every day	5-6 days a week	3-4 days a week	1-2 days a week	At least once a month	Less often than once a month	Rarely or never
☐	☐	☐	☐	☐	☐	☐	☐

Section 6 - Some information about you and your family

How would you describe your ethnic origin?
PLEASE PUT A CROSS IN ONE BOX

- White ☐
- Black British ☐
- Black Caribbean ☐
- Black African ☐
- Black Other ☐
- Indian ☐
- Pakistani ☐
- Bangladeshi ☐
- British Asian ☐
- Chinese ☐
- Other ☐

Is the accommodation you live in owned, rented or being bought on a mortgage?
PLEASE PUT A CROSS IN ONE BOX

Owned/mortgaged by you or your family..... ☐
Rented from the council..... ☐
Rented from a housing association..... ☐
Privately rented..... ☐
Other..... ☐

Please look down this list and put a cross next to the **FIRST QUALIFICATION** you come to that you have passed?
PLEASE PUT A CROSS IN ONE BOX ONLY

Degree or equivalent..... ☐
Teaching or other qualification..... ☐
'A' level or equivalent..... ☐
GCSE, 'O' level or equivalent..... ☐
CSE or equivalent..... ☐
CSE ungraded..... ☐
Other qualifications..... ☐
No qualifications..... ☐

What is your marital status?
PLEASE PUT A CROSS IN ONE BOX

Married..... ☐
Living as married..... ☐
Single/never married ☐
Widowed..... ☐
Divorced..... ☐
Separated..... ☐

Is there a car or van normally available for use by you or any members of your household?
PLEASE PUT A CROSS IN ONE BOX

Yes ☐ No ☐

Which of the following best describes your current situation?
PLEASE PUT A CROSS IN ONE BOX

- Working for an employer full time (more than 30 hours per week) .. ☐
- Working for an employer part time (less than 30 hours per week).... ☐
- Self-employed..... ☐
- Retired from paid work for an employer..... ☐
- Retired from self-employed work..... ☐
- Unemployed/redundant and looking for work..... ☐
- Permanently sick or disabled and not able to work..... ☐
- Looking after the home or family full-time..... ☐
- Student or on a training course..... ☐

→ Please go to question 29.

How would you describe your present job?
PLEASE PUT A CROSS IN ONE BOX

Manual ☐ Non manual ☐

Today's date ☐☐ ☐☐ ☐☐☐☐
Day Month Year

ANK YOU FOR COMPLETING THE QUESTIONNAIRE. PLEASE RETURN IT IN THE PREPAID VELOPE.

Appendix C

Invitation Letter to Baseline Health Check

«FirstN2» «Surname1»
«Address_1»
«Address_2»
«Address_3»
«Postcode»
«PATID»

6th January 1996

Dear «FirstN2»,

We recently sent you a questionnaire as part of some research we are doing with the doctors at The Redwell Medical Centre which you kindly returned.

We are now inviting people to attend a routine health check at the medical centre. The health check will involve talking through the questionnaire and a few physical measures (such as blood pressure). It will not involve taking any blood and will take a maximum of 30 minutes.

We have booked you an appointment for: ____ / ____ / ____ at _____ am/pm.

If you are unable to attend this appointment please call Gerald Dove on 01604 33782.

NB. Please do not call the medical centre as they are not responsible for any of the appointments.

I look forward to meeting you in the near future.

Sincerely

Charlie Foster
Research Assistant

Appendix D

Reminder Letter to Baseline Health Check Non-Attenders

«FirstN2» «Surname1»
«Address_1»
«Address_2»
«Address_3»
«Postcode» «PATID»

27th January 1997

Dear «FirstN2»

I notice from our records that you were unable to attend your recent health check appointment. I hope all is well with you.
Another appointment has been booked for: ____ / ____ / ____ at _____ am/pm.

The health check will involve talking through the questionnaire and a few physical measures (such as blood pressure). It will not involve taking any blood and will take a maximum of 30 minutes.

If you are unable to attend this appointment please call Gerald Dove on 01604 33782.

NB. Please do not call the medical centre as they are not responsible for any of the appointments.

I look forward to meeting you in the near future.

Sincerely

Charlie Foster
Research Assistant

Appendix E

Intervention Protocols for Brief Negotiation & Direct Advice

Brief Negotiation Protocol

WELCOME

CHECK DETAILS

Thanks for sending in your questionnaire and coming in today.

What I'd like to do today is to go through this questionnaire with you and measure your weight, height and blood pressure. In a moment we'll do the measurements and then we'll talk through the questionnaire. First of all I have to tell you that in conjunction with the medical centre we are carrying out a study which we would like you to take part in. On this sheet are details of the study, which I'll go through with you *(give consent form).*

Have you any questions?

Thank you for agreeing to take part.

Before we begin, I'd like to just explain a little about how we will be working together. It's not my job today to try and make you change. I hope that I can help you to think about your lifestyle and consider what, if anything, you might want to do, but if there is any changing, ***you*** will be the one who does it. Nobody can tell you what to do; nobody can make you change. I'll be giving you some information about some of the things on the questionnaire, but what you do with that after you leave is completely up to you. The only person who can decide whether and how you change is you. How does that sound to you?

What we'll do now is measure your height, weight and blood pressure. *(Feed back neutrally).*

Next we'll go through the questionnaire and as you can imagine there's a lot of information there.

I see from what you've filled in on the questionnaire that you appear to be in good health and you don't have any long-standing illnesses.

You...smoking status
You...drinking status, including units
You...food use, spreads & veg.

Is that right so far, or have I missed anything?

Strategy 1 - Typical day/week

An area we are particularly interested in, is the amount of physical activity that people do. You may have noticed that there were quite a few questions around this.

Can we spend the next few minutes talking about your current physical activity so that I can better understand how it fits into your everyday life?

Think of a fairly typical (recent) day which would give me a good picture of your usual routine.

Can you think of one?

I'd like you to take me through this day, a step at a time, and tell me how physical activity fits into the day.

Reflective listening and summary

Strategy 2 - Assessment of Motivation & Confidence

I wonder....., thinking about today and what we've already talked about, how motivated would you say you are right now to take up regular exercise? Could you mark a place on this scale between 0-10?

If you did decide to take up regular exercise, and as I said that's a decision only you can take, how confident are you that you would be able to do it? Could you mark a place on this scale between 0-10?

Okay, that's interesting, thanks. I wonder if we could just go back a minute. I notice that the score you gave for motivation was about 4, I wonder why not 0 or 1?

Reflective listening and summary

And what kind of things would have to change in order for you to be able to say a higher score, say 8 or 9?

Reflective listening and summary

And should you decide to take up exercise you'd be here on the confidence scale. 4, 5 etc.

I wonder why that and not 1?

Reflective responses and summary

What things would have to change for you to feel more confident?

Reflective responses and summary

SUMMARISE BOTH SCALES USING CLIENT LANGUAGE

Strategy 3 - Pros and Cons of taking up regular exercise

Let's just imagine for a moment that you and I were meeting again in 6 months time, and during that time you had been doing regular exercise. How do you think you might have benefited from doing that?

Reflective listening

What might you not like or what might be difficult about doing regular exercise?

Reflective listening

NB. If time is raised as a barrier possible responses include.

It sounds from what you're saying that to fit exercise in, you'd have to give up/do less of, some things that might be quite important to you. What kind of things might these be?

What would have to change in order for you to fit exercise in? ..... and that would be quite difficult.

SUMMARISE PROS & CONS

Strategy 4 - information giving

This is an opportunity to add other benefits to the pros side of change that were not brought up by the client.

I wonder if you would be interested in learning/knowing a bit more about the benefits of regular exercise that people often describe or say and what research tells us?

More active people have about half as much heart disease than less active people.
They also tend to have stronger bones.
People who take more exercise tend to have lower blood pressure, lower cholesterol levels, less depression and anxiety, and generally report that they 'feel better' etc., etc.,

What do you make of that?

Strategy 5 - Exploring Concerns

What about if, as we said before, we were meeting again in six months or so and during that time you hadn't done any exercise or very little. What might concern you about that?

Reflective listening

SUMMARISE ALL SIDES OF DECISIONAL BALANCE THEN ASK....

Where do you think we go from here?
What do you think the next step is?

If the client responds "I don't know" or "I'm unsure...

Summarise what the options are.
Change - No change - Take less exercise - Think about it more - Consider Options for Change

Strategy 6 - Helping with Decision Making

The good news is that there isn't just one way of becoming more active. There are many different ways of taking up regular exercise. Some people like some types of exercise and not others. Shall we see what some of the options are?

What kind of things could you imagine yourself doing?

If the client wants you to come up with the options try to avoid slipping into advice giving.

What I can do is tell you what other people have found they enjoyed doing and then we can see if you think any of those things might work for you. Is that okay?

What a lot of people seem to get along with okay is brisk walking?

Reflective listening

Once a number of options have been identified, go through each of them.

Which one of these seems most realistic to you?
How do you think that would turn out if you did choose that option?

How many times per week do you think you might be able to do that?

.....and how long do you think you might spend on each occasion?

Summarise what is agreed and convey willingness to re-examine. If this one doesn't work out there are other options that you could try.

Brief Advice Strategy Plan

WELCOME

CHECK DETAILS

Thanks for sending in your questionnaire and coming in today.

What I'd like to do today is to go through this questionnaire with you and measure your weight, height and blood pressure. In a moment we'll do the measurements and then we'll talk through the questionnaire. First of all I have to tell you that in conjunction with the medical centre we are carrying out a study which we would like you to take part in. On this sheet are details of the study, which I'll go through with you *(give consent form).*

Have you any questions?

Thank you for agreeing to take part.

What we'll do now is measure your height, weight and blood pressure. *Feed back neutrally.*

Next we'll go through the questionnaire and as you can imagine there's a lot of information.

I see from what you've filled in that you appear to be in good health and you don't have any long-standing illnesses.

You...smoking status
You...drinking status, including units
You...food use, spreads & veg.

Outline of new PA recommendations

I see from your questionnaire that you currently do not take much exercise.

The recommendation is that all adults should aim to build up towards 30 minutes of exercise on most days of the week, at least 5 days per week. The 30 minutes can be broken down into two lots of fifteen minutes per day. The exercise needs to be hard enough to raise your heartbeat and leave you slightly out of breath. An example of how to meet the recommendation would be a 2 mile brisk walk on most days of the week.

Do you understand that?

Health Risks of Inactivity

The recommendation is based on research that shows that people who do very little exercise have about double the rate of heart disease compared to those who meet the recommendation. Also, people who don't take much exercise are more at risk of developing high blood pressure, high cholesterol, diabetes, osteoporosis and seem not to cope so well with stress.

Advantages of Increased Physical Activity

By becoming more active you will have a lower risk of developing the conditions already mentioned and will feel more energetic, less out of breath doing day to day tasks, be able to manage your weight better and generally have a better sense of well being.

So you can see why it is important to be clear about your current potential problems of not exercising and how you would benefit from doing more.

Can you see that?

Now, the best way of becoming meeting the new recommendation is to do more walking because the recommendation means exercise doesn't have to be too hard. Also, walking doesn't cost any money and doesn't require you to turn up at a facility or special class.

How could you go about doing more walking?

Suggest mornings (on the way to work etc.) lunch times, after work.....with their partner, friend.....

Now the recommendation also suggests doing some exercise on at least five days of the week. How many days of the week do you think you could go and do a walk at the moment? Perhaps you could start off by just doing a 1 mile walk each day. That would only take about 15 minutes.

Now remember that we said that the walk had to be brisk. One really good way of being able to check this is called the talk test.

This means that when you are out walking, it should be brisk enough so that if you tried to talk to someone it would be quite difficult but you could still do it. If the walk is so hard that you can't talk, then you should slow down. Do you understand what I mean (demonstrate laboured talking).

When you first start walking begin slowly and build up gradually to the main pace. This is important for safety. A bit like speeding your car up by going through the gears one at a time. You don't just put it into fourth gear and try and pull away. And then when you are coming to the end of a walk, gradually walk slower and slower until you come to a halt. Warming up and cooling down should take you about 2-3 minutes each.

Question & Answer

Any questions or things you'd like me to explain again?

RESPOND WITH SPECIFIC ADVICE

If clients raise reasons why they can't do exercise or can't find it in, reinforce how little 30 minutes a day is and encourage they to really try and fit it in.

Give instruction on appropriate foot wear and inform them that they should contact you should they have any concerns about safety.

Appendix F

Log Book Sample Page

ıe Redwell Medical Centre

ysical Activity Diary

›hysical activity diary is for you to record your physical activity/exercise in. Each page in the diary ents one day. On each page write in the day and date in the space provided. The diary has one page for lay of the week.

do not do any physical activity on a particular day, write in the day and date and then leave that page

ıch day that you do some physical activity you should record:

ıe day and date
hat activity you did by **putting a cross** in the relevant box.
›w long you did the activity for by **writing the time in minutes.**
›w hard the activity was by **putting a cross in one or more boxes** labelled 'warm', 'perspire' or 'breathe ırd' (from this selection you can tick one, two or three boxes, depending on how hard you felt the activity ıas).

ıple:
ay 2nd October

ACTIVITY	Put an 'X' in the box for each activity carried out	Duration of activity (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
ING						
g at a slow pace						
g at a steady average pace						
g at a fairly brisk pace	X	45	X			
g at a fast pace						
g with heavy shopping						

xample shows that on Monday 2nd October, walking at a fairly brisk pace was done for 45 minutes. The ıg made the person warm, but they did not perspire or breathe hard.

lease fill the diary in each day. If you leave it until the end of the week, you may not be able to remember ıtely all the activities that you did.

you have completed the diary, please return it in the pre paid envelope.

Day of the week
(e.g. Monday, Tuesday etc.)

Date (e.g. 2nd October)

ACTIVITY	Put an 'X' in the box for each activity carried out	Duration of activity (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
ENING AND DIY						
g, weeding, pruning						
g with a power mower						
g with a hand mower						
g flowers/seeds						
g, clearing rough ground						
al building work						
ating						
household repairs						
ashing and polishing						
pairs and maintenance						
please specify						
ING						
g at a slow pace						
g at a steady average pace						
g at a fairly brisk pace						
g at a fast pace						
g with heavy shopping						
EWORK						
aking						
g heavy furniture						
cleaning						
ng windows						
ring						
g						
ng floors						
please specify						
TS AND RECREATION						
cs/keep fit						
g						
training						
ning						
g/jogging						
ll/rugby						
nton						
g						
please specify						

Appendix G

Invitation Letters to Follow Up Health Check for Intervention and Control Group Subjects

«FirstName2» «Surname»
«Address_1»
«Address_2»
«Address_3»
«Address_4» «Postcode»
«PATID»

29th July 1998

Dear «FirstName2»,

It's approximately a year now since you came in for a health check and kindly agreed to take part in our study with the doctor's at Albany House Medical Centre. We are at the last stage of the study now and would like to repeat some of the measures we took last time.

Repeating the checks we made before is a very important part of the study and essential to its completion. Therefore, I would be grateful if you could spare me the time to call in to the medical centre for **one last time.**

I have booked you an appointment for : ____ / ____ / ____ at _____ am/pm.

If you are unable to attend this appointment please call Gerald Dove on 01604 633782.

Thank you for your continued support of our project and I look forward to seeing you again soon.

Sincerely

Charlie Foster
Research Assistant

«FirstName2» «Surname»
«Address_1»
«Address_2»
«Address_3»
«Address_4» «Postcode»
«PATID»

1st April 1998

Dear «FirstName2»,

You may remember that last year we sent you a lifestyle questionnaire as part of some research we are doing with the doctors at Albany House Medical Centre which you kindly returned.

We are now inviting people to attend a routine health check at the medical centre. The health check will involve a few physical measures (such as weight and blood pressure). It will not involve taking any blood and will not hold you up for very long.

We have booked you an appointment for: ____ / ____ / ____ at _____ am/pm.

If you are unable to attend this appointment please call Gerald Dove on 01604 633782.

NB. Please do not call the medical centre as they are not responsible for any of the appointments.

I look forward to meeting you in the near future.

Sincerely

Charlie Foster
Research Assistant

Appendix H

Reminder Letter to Follow Up Health Check Non-Attenders

«FirstName2» «Surname»
«Address_1»
«Address_2»
«Address_3»
«Address_4» «Postcode»
«PATID»

19th September 1998

Dear «FirstName2»,

I notice from our records that you were unable to attend your recent follow up health check appointment. I hope all is well with you.

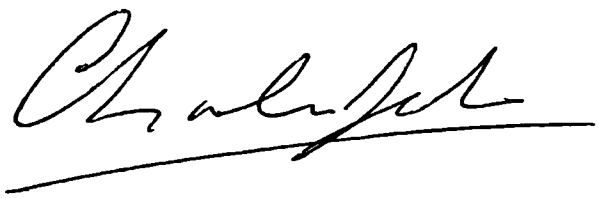
This is the last stage of our study with the medical centre and repeating the checks we made before is essential to completing our work. Your information is extremely valuable and I would very much appreciate it if you could spare the time to call in to the medical centre for a maximum of 10 minutes .

I have booked another appointment for : ____ / ____ / ____ at _____ am/pm.

If you are unable to attend this appointment please call Gerald Dove on 01604 633782.

Thank you for your continued support of our project and I look forward to seeing you again soon.

Sincerely



Charlie Foster
Research Assistant

Appendix I

Relevant Publications

Reprinted from Journal of Epidemiology & Community Health, October 1995, Vol 49, No 5, p 448-453

Review article

Randomised controlled trials of physical activity promotion in free living populations: a review

Melvyn Hillsdon, Margaret Thorogood, Tim Anstiss, Jerry Morris

Abstract

Objectives **– To review evidence on the effectiveness of trials of physical activity promotion in healthy, free living adults. To identify the more effective intervention programmes.**

Methods **– Computerised databases and references were searched. Experts were contacted and asked for information about existing work.**

Inclusion criteria **– Randomised controlled trials of healthy, free living adult subjects, where exercise behaviour was the dependent variable were included.**

Conclusions **– Ten trials were identified. The small number of trials limits the strength of any conclusions and highlights the need for more research. No UK based studies were found. Previously sedentary adults can increase activity levels and sustain them. Promotion of these changes requires personal instruction, continued support, and exercise of moderate intensity which does not depend on attendance at a facility. The exercise should be easily included into an existing lifestyle and should be enjoyable. Walking is the exercise most likely to fulfil these criteria.**

(*J Epidemiol Community Health* 1995;49 448–453)

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A recent meta-analysis of physical activity as a risk factor for coronary heart disease concluded that the relative risk in the least active compared with the most active was 1·9.[1] Though this relative risk is similar to the risk of other factors, the prevalence of inadequate physical activity at around 70%[2] of the English population is greater than the 31% who smoke, 30% with a raised serum cholesterol concentration, and 15% who are hypertensive.[3]

There are randomised, controlled trials using exercise as an intervention in the management of health problems, notably hypertension, hyperlipidaemia, and overweight. These have demonstrated the importance of exercise in the management of disease. However, because their outcome variables are biological and physiological rather than exercise, they do not increase our knowledge of effective programmes to increase physical activity. They are therefore not included in this review.

We report a systematic review of randomised controlled trials of physical activity promotion in apparently healthy free living adults (that is, people who were not receiving treatment for any illness and were not in an institution). The aim was to explore evidence of effective promotion of physical activity.

Methods

Searches were carried out using *Medline*, *Excerpta Medica*, *SPORT* (Data-Star), and *Unicorn* from 1966-93. Key words include "exercise", "community", "intervention", and "randomised controlled trial". Searches were also carried out on key authors identified from reviews. Only English language journals were searched. Two hundred and fifty abstracts were identified but only 18 described papers on randomised controlled trials. Additional searching was then carried out using the references from both existing reviews and the papers chosen from the abstracts. A further 37 papers were thus gathered. Each paper was read by two of us (MH and TA) and considered for inclusion.

The criteria for inclusion were as follows:

- A control group;
- Subjects were assigned to control or intervention by randomisation;
- Trials testing single factor interventions to increase activity;
- Interventions tested on apparently healthy, free living adults;
- Exercise behaviour was the dependent variable.

The quality of each paper was assessed using a three point scoring system. Each of three areas of potential bias in methodology were scored: (1) the quality of random allocation; (2) results analysed on intention to treat; (3) outcomes assessed without knowledge of assignment of subjects to groups by randomisation. Each of these areas then received a score of "0" or "1", allowing for a maximum quality score of 3 or a minimum of 0.

Summary of interventions

Authors, year of publication, stated objectives	Length of intervention	Authors description of exercise	Prescribed frequency, intensity, and duration of exercise	Professional contact and behavioural technique	Controls
Hoyt and Janis 1975[4] To test whether a relevant balance sheet compared to an irrelevant balance sheet would result in higher attendance at an exercise group.	7 wk	Exercise class	Not stated	None after initial telephone contact Decisional balance sheet	No treatment
Reid and Morgan 1979[5] To assess the effectiveness of physician prescribed exercise programme with health education and self monitoring components.	1 h	Endurance activity	Advice about frequency, intensity, duration given but not described.	Physician exam and personal exercise advice Health educator presentation plus video and self monitoring. 1 12 report on exercise programme.	Assessment and written exercise advice
King and Frederickson 1984[6] To study the effect of two low cost methods of increasing the number of participant controlled jogging episodes	5 wk	Jogging	4 × wk, individualised time and distance goals	Team building exercises and relapse prevention training for different groups.	Instructed to jog alone
MacKeen *et al* 1985[7] To study the effects of an 18 month exercise intervention on adherence.	18 mth	Jogging, swimming, games	3 × wk minimum, 35–75 min per session.	Occasional risk factor meetings with wives, no adherence technique.	Assessment only
Kriksa *et al* 1986[8] To examine factors associated with exercise compliance in post menopausal women	2 y	Walking	3 × wk, brisk, 3 ml per session.	Supervised walking sessions, social gatherings, telephone contact, self monitoring and rewards	Assessment only
King *et al* 1988[9] To evaluate strategies for enhancing the adoption and maintenance of exercise training by healthy middle aged men and women	6 mth	Walking and jogging	4 × wk at 65–77% peak heart rate for 30 min per session.	Telephone contact, self monitoring and instructions on relapse prevention and adherence.	No assessment only controls
Noland 1989[10] To assess effects of behavioural techniques on adherence to unsupervised exercise	18 wk	Walking, jogging and swimming as preferred	3 × wk at 30 40% or 60–70% VO_{2max} for 30 min.	2 Telephone contacts + reminders if activity logs late. Self monitoring and rewards.	Assessment + advice + telephone support
King, Haskell *et al* 1991[11] To determine the effectiveness of group vs. home based training of higher and lower intensities	1 y	Walking and jogging	Two groups 3 × wk at 73–88% peak heart rate for 40 min per session, one group 5 × wk at 60–73% peak heart rate for 30 min each session.	Supervised exercise for facility based arm, telephone contact for home based. Self monitoring.	Assessment only
Suter and Marti 1992[12] To identify factors related to both exercise adoption and long term adherence to a home based jogging programme	4 mth then crossover	Walking and jogging	2–6 × wk at 85% of heart rate at anaerobic threshold for a total of 120 min per wk.	Telephone contact and personal feedback. Self monitoring and individual exercise prescription.	Waiting list
Marcus and Stanton 1993[13] To assess effectiveness of a relapse prevention programme and reinforcement programme in increasing exercise adherence and short term maintenance	18 wk	Exercise to music class	3 weekly classes beginning at 35 min and progressing to 50 min duration.	Weekly exercise class. Relapse prevention training, reinforcement and lottery.	Attendance at exercise group, no behavioural technique

Results

Ten papers met the inclusion criteria and are listed in table 1. Only two of the papers were found from the computer searching. Nine trials were from the USA with one from Switzerland. None were from the UK. Most subjects were volunteers who responded to advertisements and were predominantly white, well educated, white collar workers. Overall, there was an even distribution between men and women with an age range of 24–72 years (mean age approximately 49 years).

INTERVENTIONS

A summary of the interventions is shown in table 1.

Length of intervention

Interventions ranged from one hour to two years and from a single educational session to regular contact with subjects.

Professional contact

In home based trials subjects usually received initial face to face instruction, which varied from simple exercise advice to the teaching of behavioural skills. Subjects attending facility based programmes and classes could have had more professional contact but no studies reported whether subjects did have such additional contact.

Subjects in home based interventions were usually telephoned after initial instruction.[8 9 11] This was sometimes for support and problem solving counselling. In other cases, however, subjects were telephoned only if they did not return self monitoring forms. No details of these calls are provided and we do not know if they were perceived as supportive.

Behavioural techniques

Self monitoring and relapse prevention training have been developed by researchers in addictive behaviours for increasing adherence to behaviour change. The two techniques were frequently used to change exercise behaviour.

Exercise variables

Most programmes were home based; only four trials used a designated facility.[4 6 7 13] Most of the trials involved jogging or walking, or sometimes the choice of either. Where these were not used, the activity was an exercise class or an unspecified aerobic activity. Subjects were asked to exercise between three and five times per week. The *intensity* of the exercise was often unspecified. When specified it was "moderate" except for jogging which was more vigorous, at approximately 80% of maximum heart rate.[12]

ble 2 Summary of results

idy	*Quality score (0–3)*	*No in study*	*Subjects*	*Post intervention follow up*	*A tual frequency intensity and duration of exercise intervention group*	*Main outcomes p<0·05*
	2	50	W ves of graduate students	Nil	Mean frequency 1 7 wk	Subjects in *relevant* balance sheet group attended approximately twice as frequently as the *irrelevant* balance sheet and control group.
	1	124	Male firefighters aged 24 56 y	3&6 mth	Not stated	No significant difference between groups at 2 mth follow up
	1	58	18–20 y old, previously sedentary, female psychology students	2 mth	Mean frequency JAR and G 2 4 wk, GR 1 4 wk	83% of jogging alone + relapse subjects still exercising at follow up compared with 36 of control subjects. No significant difference between groups on post study fitness levels
	1	315	Males aged 53–72 y with one or no risk factors for CHD	12 y	Mean hours jogging/wk at year 13 0 3 h.	No difference between exercise and control conditions at follow up on jogging hours per week.
	2	229	Post menopausal women aged 50–65 y	Annually	Mean miles walking/wk 8 4 Mean energy expenditure 1514 kcal/wk	Self reported walking level significantly higher at year 1 & 2 compared with controls
	1	103	52 male and 51 female, middle aged subjects	Nil	Adoption arm mean of 3 sessions/wk for 32 min Maintenance arm mean of 2·9 sessions/wk for 37 min	Adoption arm subjects receiving telephone support showed significant increase in VO ₂max. Maintenance arm – daily self monitoring resulted in greater exercise frequency than weekly self monitoring.
	1	77	28 men (mean age 40) and 49 women (mean age 36)	Nil	Self monitoring group mean of 2·4 wk for 26 mins. Reinforcement group mean of 2 5 wk for 29 mins.	Increase in VO_{2max} in all three conditions Behavioural interventions increased frequency of exercise compared to controls.
	2	357	160 women and 197 men aged 50–65 y. Predominantly white and well educated	On-going	Mean frequency HIG ~ 1·2/wk HIH ~ 2/wk LIH ~ 3 wk	Increase in Vo_{2max} in all exercise groups. Higher adherence in both home based conditions No changes in other CHD risk factors
	1	61	Middle or upper class, middle aged, apparently healthy, male bank workers	4 mth	Mean of 12·9 km wk.	Only changes in vigour on psychometric test significantly correlated with 8 mth activity levels No significant differences in lipids, blood pressure, body composition or endurance capacity.
	1	120	Previously sedentary, female university employees with a mean age of 35 y and mean body mass index of 25	2 mth	Percentage of classes attended during the 18 wk RP = 51%, R = 49%.	No significant difference in attendance at 18 wk or 2 mth follow up.

R = jogging alone + relapse prevention; G = group jogging; GR = group jogging + relapse prevention; HIG – high intensity group; HIH high intensity home; H = low intensity home; RP – relapse prevention; R – reinforcement.

Where duration of prescribed exercise was specified it ranged between 15 and 75 minutes.

Sustained improvement

The development of coronary heart disease is a long process and evidence suggests that the health benefits of exercise cannot be saved up, so people must continue to exercise if they are to maintain their protection from coronary heart disease. Therefore, in this review more attention is paid to those trials with longer follow up periods.

ASSESSING OUTCOMES

Few studies included follow up of the subjects after the intervention. Of those which did, the average period was eight months with the exception of one trial which had a follow up period of 12 years.[7] Definitions of *good adherence* ranged from exercising twice a week for 15 minutes to 7 miles of walking per week, or 100% of the prescribed sessions. Two trials measured VO_{2max} (the highest oxygen uptake attained during exercise involving large muscle groups).[14]

OUTCOMES

Table 2 shows the main outcomes.

Professional contact

Study 6 in table 1 varied the frequency of telephone contact and observed that subjects who received most contact exercised more frequently, for slightly longer, and achieved greater values than subjects receiving less contact and controls.[9] In a later trial,[11] the same team telephoned subjects performing home based exercise regularly, and compared adherence with that of subjects attending a facility based programme. After one year 79% and 75% of subjects in two home based groups were achieving over three quarters of prescribed exercise, compared to 53% of subjects randomised to a facility.

Study 5 in table 1, a trial of post menopausal women walking, in which professional contact was a major component, achieved high adherence at two years.[8] Sixty one per cent of women in the intervention group were exercising at the level prescribed and four fifths were achieving 70% of the prescribed level, an increase in self reported walking over baseline of 79% compared with 16% in the control group.

Self monitoring

In trial 10 (table 1) subjects were randomly assigned to three groups, one of which was taught self monitoring techniques.[13] There was a low adherence rate at six months and the authors concluded that "self monitoring did not produce a further increase in compliance". However, 55% of the self monitoring subjects did not complete their records. Those who did, achieved an adherence rate of 56% nearly double that of the other treatment group. It is impossible to know whether subjects were reluctant to complete the record or were not undertaking the exercise. Trial 6, took subjects

from an earlier trial and randomised them to two 'maintenance' groups with different frequency of self monitoring. During the next six months, subjects completing daily self monitoring forms performed 35% more exercise sessions that subjects completing weekly forms.

Relapse prevention

Relapse prevention training was used in several trials but not described in detail. In trial 3, a trial of jogging alone or in a group and of jogging with and without relapse prevention training, 83% of subjects with relapse prevention in the two jogging alone arms were still exercising at three months compared with 36% of those without this training.[6] In the two group jogging arms, however, there was no significant difference in the group with relapse prevention training, with 39% of subjects exercising in both groups.

Relapse prevention was compared with reinforcement strategies in trial 10, a study of women attending 18 weekly exercise classes.[13] Subjects in the relapse prevention group received 18 weekly sessions on relapse prevention, including a planned 10 day break from exercise at nine weeks to demonstrate the possibility of lapsing and restarting exercise. Subjects in the reinforcement group received T-shirts and other rewards for attendance, while controls subjects simply attended the exercise class. Attendance was not significantly higher in either intervention group compared with controls with the attrition rate (attendance at less than two thirds of exercise sessions) for all groups averaging 72% at 18 weeks.

Location of exercise

Trial 8 compared facility and home based programmes of different exercise intensities.[11] The home based groups completed significantly more exercise sessions than the facility based group.

Exercise frequency

At the end of the trials those subjects still exercising were usually exercising around twice per week. One trial found that subjects prescribed three exercise sessions per week achieved higher adherence rates than those prescribed five at two year follow up.[15]

Exercise intensity

Few details of exercise intensity at follow up were reported. When they were, subjects exercised within the prescribed range (measured using telemetry heart rate monitors). Trial 8, a study with both high and low intensity groups, found that the high intensity group preferred to train at the bottom of their target heart range while the low intensity group preferred to exercise at the top of their range.[11] Thus, both groups moved towards moderate intensity exercise.

VO_{2max}

In trial 6, subjects increased their VO_{2max} values by 7% to 8%.[9] In trial 8, subjects in all three intervention arms who performed greater than 75% of prescribed exercise sessions improved their VO_{2max}.[11] In the two high intensity arms subjects improved by 7% and 9% respectively while in the low intensity arm they improved by 5%. These physiologically significant changes were achieved by easily performed moderate intensity exercise.

Discussion

The wide variation in methodology and definitions of adherence in these few trials, make a formal meta-analysis unhelpful. The important public health question is whether attempts to modify exercise behaviour result in health gain in sufficient numbers of people to make these cost effective, and this review suggests that it is possible to increase the exercise levels of sedentary subjects. Trials that showed sustained high levels of participation (studies 5, 6 and 8) shared a number of common features.[8 9 11] These are:

- Home based programmes;
- Unsupervised, informal exercise;
- Frequent professional contact;
- Walking as the promoted exercise;
- Moderate intensity exercise.

Home based interventions were more successful than facility based programmes. One study (number 7) compared facility and home based exercise; the home based groups achieved significantly more exercise sessions.[10] Another home based study (number 6) showed a positive relationship between the convenience of exercise and its adoption and maintenance, and this may explain why home based exercise seems preferable.[9]

Subjects who exercised alone completed more exercise sessions that those who exercised in groups. In a short jogging trial (number 3 table 1), subjects assigned to jogging alone with relapse prevention training performed over double the exercise of subjects who exercised as a group and were taught cohesiveness skills.[7] The inconvenience of meeting at a specific time and place may reduce adherence to group based programmes.

High participation (studies 5, 6, 8) was also associated with frequent professional contact.[8 9 11] Contact was usually made by telephone or occasionally by home visits. The amount of contact was not great. In one trial (number 6) subjects received less than 60 minutes of total telephone contact over 6 months.[9] In another study (number 8) the authors reported an average of 15 telephone contacts of approximately three minutes over one year.[11] The two home based arms which received telephone support performed significantly more exercise than the group based arm which did not.

The interaction between professional and client may be of greater importance than any behavioural technique. Addictive behaviour re-

searchers have found that the way in which a therapist interacts with a client is a better predictor of treatment outcome than either the client characteristics or the therapist's theoretical orientation.[16] A review of therapist effectiveness with substance use disorders concluded that good interpersonal skills of the therapists was associated with high effectiveness.[17]

Three successful trials used walking, which is already a popular form of exercise[9,10] and does not require special equipment, a formal facility, or fellow participants. The promotion of exercise which is popular and can be incorporated into existing lifestyles may be more successful. Walking is normally a moderate intensity activity, and moderate intensity is associated with higher participation. Even subjects randomised to *high* and *low intensity* exercise may prefer moderate intensity. In one trial, subjects assigned to high intensity exercise, exercised at a mean rate of perceived exertion (RPE – a validated, subjective rating of exercise intensity) of 13,[18] whereas those assigned to low intensity exercised at a mean RPE of 11·7 (study 8), both moderate intensity levels.

A lesser frequency of prescribed exercise was associated with better maintenance. In study 3, subjects were prescribed four sessions per week but at one year subjects were averaging just over two sessions per week.[7] In another trial, study 8, subjects were assigned to either five, 30 minute or three, 40 minute sessions per week. The proportion achieving over 75% of prescribed sessions did not differ at one year, but at two years the three sessions per week subjects maintained a higher percentage.[15]

These trials indicate that it is possible to increase physical activity levels in free living individuals, but that improvements in physical fitness (measured as VO_{2max}) are smaller than those found in laboratory studies.

The subjects in nine studies were volunteers who were considering increasing, or had decided to increase, their physical activity. In the one study that recruited by random digit dialling, 20 418 numbers were dialled of which only 9% yielded subjects for randomisation, mainly due to the exclusion criteria. Of those eligible, only 27% were randomised, suggesting considerable self selection.[19] While some studies have been successful they tell us nothing about promoting physical activity in people who would not have accepted an offer of participation in an exercise programme.

The four trials which continued for at least 6 months (4, 5, 6, 8) provide the basis for most of our conclusions. Subjects were all over 47 years of age, well educated, and white. Whether these results can be generalised to other populations, including those in the UK, is not known.

Some of the 55 studies identified initially but not included because of methodological problems, involved techniques which might prove useful and should be evaluated. These included concepts of self efficacy, barriers to change, support and reinforcement,[20] as well as a person's "stage of change" with regard to physical activity.[22] A further important question is whether subjects prescribed exercise as a treatment for a diagnosed condition are more likely to maintain it That is, how important is the presence of ill health to compliance with prescribed exercise.

FUTURE RESEARCH

Further experimental research is urgently needed, particularly in three areas:

- Groups other than middle aged, middle class white people, looking at those at highest risk from coronary disease who might have the greatest capacity to gain from increased activity, particularly the elderly.
- Exploring the factors that might affect both initial uptake of the activity and subsequent adherence to a new activity level in subjects resident in the UK.
- Exercise prescription to treat specific conditions.

Conclusion

It is possible to increase activity and maintain the increase at sufficient frequency and intensity for long term health gain. This is best achieved when exercise is home based, of moderate intensity, can be performed alone *or* with others, is enjoyable, convenient, and can be completed in three sessions per week. Walking will satisfy all of these criteria. Self monitoring and relapse prevention training may improve early adherence, and continuing support and reinforcement may improve long term adherence. An initial brief instructional session followed by short but frequent telephone support may be most effective. These interventions are low cost and easy to administer compared with facility based group exercise interventions where the barriers and costs associated with attendance may lead to high drop out rates.

These findings do not support the increasingly popular *prescription for exercise* schemes. A high proportion of these schemes involve general practitioners referring their patients to a leisure centre or similar facility, but we have found no evidence to support the efficacy of facility based interventions. These interventions are unlikely to be the most effective way of increasing population activity levels. Less than 1% of a practice list are referred into such schemes.[23] Although they attract publicity, organisations would be wise not to rush into *prescription for exercise* schemes until evidence is available to support their efficacy.

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VIEW ARTICLE

A systematic review of physical activity promotion strategies

Melvyn Hillsdon, Margaret Thorogood

Regular physical activity can play an important role in both the prevention and treatment of cardiovascular disease, hypertension, non-insulin-dependent diabetes mellitus, stroke, some cancers, osteoporosis and depression, as well as improving the lipid profile.[1–8] A meta-analysis of the relation between physical activity and coronary heart disease reported that the relative risk of coronary heart disease death in the least active compared with the most active was 1·9-fold.[9] The magnitude of this relative risk is similar to that of the other important cardiovascular disease risk factors, cigarette smoking, hypertension, and hyperlipidaemia.[10]

Despite this evidence, it is estimated that 70% of the English population takes inadequate physical activity[11] compared to 31% who smoke, 30% with a raised serum cholesterol concentration, and 15% who are hypertensive.[12]

In 1995 the Centers for Disease Control and Prevention (USA) and the American College of Sports Medicine recognised the importance of physical activity and published a public health message recommending that "every adult should accumulate 30 minutes or more of moderate-intensity physical activity on most, preferably all days of the week".[13] In March of this year the Health Education Authority also recognised the public health potential of physical activity, by embarking on a three year national campaign (Active for Life) at promoting the same message.

Although a large body of evidence exists about the health benefits of physical activity, far less is known about the effectiveness of strategies to achieve the increases in physical activity necessary to acquire these benefits.

In this paper we report a revised and updated version of a previous systematic review of randomised controlled trials of physical activity promotion in apparently healthy, free living adults.[14] The aim of the paper is to provide recent and reliable information on the effectivene s of physical activity promotion.

There are randomised, controlled trials using exerci e a an intervention to study the physiological effects of exercise and in the management of health problem , notably hypertension, hyperlipidaemia, and overweight. These how the effects of exercise on various phy iological and biological outcomes and demonstrate the importance of exercise in the management of disease However, becau e the main outcome of such trials is not physical activity, they do not help us understand the effectiveness of physical activity promotion strategies. For these reasons they were not considered for this review.

Methods

Computerised searches were carried out using Medline, Excerpta Medica, Sport, and SCISearch from 1966–1996. The method described by Dickersin and colleagues[15] was used to search for randomised controlled trials on Medline. Key words for searching included "exercise", "physical activity", and "Randomised-Controlled-Trial". The search was limited to English language journals. Additional searching was carried out using the references from both existing reviews[16–18] and the papers identified during the search. In addition to the studies described previously, a further 10 studies were found. Those studies included in the previous review were reread by both of us independently, as were the new studies identified during this search. Each paper was read and assessed using a shortened version of the EPI-Centre Review Guidelines.[19]

The criteria for inclusion of trials in the review were:

- a control group
- subjects assigned to control or intervention by a process of randomisation
- trials testing single factor interventions to increase activity
- interventions tested on apparently healthy, free living adults
- minimum of 12 weeks duration
- exercise behaviour was the dependent variable

Results

Ten new trials were identified, with three meeting the inclusion criteria. Two of the 10 trials in the earlier review were excluded. One of these[2] did not meet the new criterion of 12 weeks minimum durati n and we decided on rereading that the other did not describe the exercise level of the control group postintervention.[21] The 11 trials which are included in this review are described in table 1A and B studies 5 and 6 are from the same paper and are reported separately for convenience). All the trials were from the USA. We did not find any from the United Kingdom

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that met the inclusion criteria, although we are aware of some that are in progress. Subjects were mainly white, middle aged, and well educated. Most subjects were volunteers, recruited through local advertisements. The trials include an even mix of males and females with an age range of 18 72 years (mean approximately 49).

INTERVENTIONS

Table 1 summarises the main exercise components of the trials and table 2 the results. Both tables are sorted by location (home or facility) of exercise and then by outcome. Intervention periods ranged from five weeks to two years. Seven of the trials included postintervention follow up periods which ranged from two months to 12 years. Most outcomes were analysed on an intention to treat basis. In the trials, subjects were asked to exercise between three and five times per week for 20–60 minutes. Few studies described the exercise intensity, but when it was described there was a mixture of moderate and vigorous intensities.

Location of exercise

The location of the prescribed exercise was the home for seven of the trials (table 1). By "home location" we refer to exercise that can take place in proximity to the subjects' homes rather than within their homes. Five of the home based trials (studies 1–5) reported a positive outcome of the intervention. One of the trials (study 6) not showing a significant difference between groups was a comparison between subjects receiving telephone contact and those not receiving it. All of the subjects were sedentary at baseline and significantly increased their exercise level during the intervention. Those subjects receiving telephone support exercised more than those who did not, but the difference did not reach significance. Study 7, the other home based trial which did not show a significant difference postintervention, did not involve giving specific advice to subjects about increasing their exercise. Subjects in this trial were given either a fitness test, a health appraisal, or both and were given feedback on the results. None of the three intervention groups exercised more than the control group.

Facility based trials normally required the subjects to attend specific sessions or groups at a local fitness centre or indoor track. Only two of the five facility based trials showed a significant difference between intervention subjects and controls.

Study 3 compared home based and facility based exercise. After one year, subjects assigned to the two home ba ed arms completed significantly more of the prescribed exercise sessions than subjects as igned to exercise at a facility (79 o, 75° o, and 53° o respectively), with no significant difference between the two home ba ed arms.

Components of pre cribed exer ise

In half of the trials in table 1, walking was the prescribed mode of exerci e. All of the trial showed a significant increase in exercise when compared to controls. In one study (study 1), 80% of subjects were walking an average of at least five miles per week, with 61% of subjects adhering to the prescribed level of seven miles per week at two years. Those trials in which walking was not recommended (studies 9–12) included exercise to music classes, gym based "endurance activity", and jogging. Only one of these trials study 9) showed an increase in exercise. Subjects were females aged 18–20 years, who may have tolerated the prescribed jogging better than the older groups in the other trials.

Although the prescribed frequency of exercise averaged three to five times per week, most subjects were reporting lower frequency at follow up, with an average two to three times per week. Study 3 assigned subjects to three intervention arms of varying frequencies. One of the two home based arms prescribed three sessions per week for 40 minutes at a high intensity, while the other home based arm prescribed five sessions per week at a low intensity. The third arm, where subjects exercised at a local community hall, prescribed three sessions per week. At one year there was no significant difference between the two home based arms on the percentage of prescribed sessions completed, with both completing significantly more than subjects in the facility based arm. Second year[33] follow up data show that subjects in the three times per week home based arm were able to maintain significantly higher levels of adherence than those in the five times per week home based arm who had reduced to a level similar to that of the facility based arm (68° o, 49° o, and 36% of prescribed sessions respectively). Although the two home based arms were prescribed differing intensity levels, analysis of heart rate data showed that both arms actually exercised at an intensity normally described as moderate.

Strategies for improving compliance

A range of behavioural methods was employed to improve compliance. It is difficult to measure the effect of some of these as they were often part of multifaceted interventions taught to all groups. Methods included reinforcement (rewarding subjects for successful completion), self monitoring (keeping personal records of exercise performed), and relapse prevention training (learning to cope with situations that prompt inactivity and preventing a missed session leading to a return to preintervention exercise levels . Some trials investigated the impact of such strategies with varying results.

In study 4, subjects were randomly assigned to self monitoring, reinforcement, and control arms. After 18 weeks, subjects in the two behavioural treatment arms were exercising significantly more than those in the control arm. Study 11 found no difference in exercise levels between subjects instructed in self monitoring and control subjects. Study 5 took subjects from an earlier trial and randomised them to two "maintenance" groups with different frequencies of self monitoring. Subjects completing daily self monitoring

1A Summary of interventions: home based

Authors, year of publication, stated objectives	*Length of intervention*	*Location of exercise (home or facility)*	*Authors' description of exercise*	*Prescribed frequency, intensity, and duration of exercise*	*Controls*
Kriska[22] – To examine factors associated with exercise compliance in post menopausal women	2 years	Home following initial 8 weeks	Walking	3 × wk/3 miles per session briskly	Assessment only
Lombard[23] – To determine the effect of frequency and structure of telephone prompts on frequency of walking	12 weeks	Home	Walking (group walking encouraged	3 × wk at least 20 min per session	Initial instruction
King[24] To determine the effectiveness of group v home based training of higher and lower intensities	1 year	2 groups home 1 group facility	Walking and jogging	Two group 3 × wk at 73–88% peak heart rate for 40 min per session one group 5 × wk at 60–73% peak heart rate for 30 min each session	Assessment only
Noland[25] – To assess effects of behavioural techniques on adherence to unsupervised exercise	18 weeks	Home	Walking jogging and swimming as preferred	3 × wk at 30–40% or 60 70% VO max for 30 min	Assessment and advice about exercise, no behavioural treatment
King[26] – To evaluate strategies for enhancing the maintenance of exercise training by healthy middle aged men and women also see No 6)	6 months	Home	Walking and jogging	4 × wk at 65 77 peak heart rate for 30 min per session	Same as intervention group but reduced level of self monitoring
King[26] – To evaluate strategies for enhancing the adoption of exercise training by healthy middle aged men and women (also see No 5)	6 months	Home	Walking and jogging	4 × wk at 65–77 peak heart rate for 30 min per session	Same as intervention group less regular telephone contact
Godin[27] – To investigate the effectiveness of fitness testing and health appraisal on exercise intention and behaviour	3 months	Home	Physical activity lasting 20–3 min per session	None prescribed	Assessment only

forms performed 35% more exercise sessions than subjects completing forms weekly.

Relapse prevention training was compared with reinforcement strategies in a study of females attending exercise classes (study 12). Subjects in the relapse prevention arm attended weekly lessons on relapse prevention immediately following an exercise class, while subjects in the reinforcement group received T shirts and other rewards for successful attendance at a number of classes. Control subjects simply attended the exercise classes. At 18 weeks there was no difference between groups on number of exercise sessions attended, with 72% of subjects attending less than the prescribed three classes per week.

In a trial of jogging alone or in a group, and of jogging with and without relapse prevention training (study 9), the impact of relapse prevention varied. Eighty three per cent (10/12) of subjects with relapse prevention training who were jogging alone were still exercising at three months, compared with 36% (5/12) of those without such training. By contrast, in the two group jogging arms relapse prevention training did not increase jogging frequency at follow up.

Study 3 investigated the effect of subjects' perceptions of whether they had achieved expected physical or psychological benefits after six months on subsequent exercise adherence.[34] Those subjects who reported they had achieved expected benefits completed more exercise sessions in the next six months than those who did not achieve their expectations. It seems that to maintain adherence in the long term, subjects need to perceive a physical or psychological gain from exercise.

Perhaps more important than any of these behavioural methods in achieving high rates of compliance is ongoing follow up.

2A Summary of results: home based

Data analysed by "intention to treat"	*No in Study*	*Subjects*	*Post intervention follow up*	*Actual frequency, intensity, and duration of exercise intervention group*	*Main outcome P < 0·05*	*Outcome + or 0*
Yes	229	Post menopausal women aged 50–65	Annually	Mean miles walking/wk = 8 4	Self reported walking level significantly higher at years 1 and 2 compared to control	+
Yes	135	University staff and faculty members, mean age 4 , mainly female	12 weeks	46% of frequent prompt groups walking 3 × 20 min per week. 13 of low frequency prompt 4 controls	Frequent telephone contact improved adherence to walking proramme	+
Yes	357	16 women and 197 men aged 50–65 Predominantly white and well educated	Ongoing	Mean frequency = HIGH 1 2 × wk, HIH 2 × wk LIH 3 × wk	Significant difference between intervention and control groups plus significant difference between home based and fall back group	+
No	77	28 men mean age 40 and 4 women mean age 36	Nil	Home training group mean f 4 each for 6 min Reinforcement group mean of 5 each for 29 min	Behavioural intervention increased frequency of exercise compared to control	+
Yes	51	Male and female middle age subject	Nil	11 4 session month for duration of month training group 3 session month for month group weekly monitoring group	Significant difference in number of exercise sessions month between group	+
Yes	52	Male and female middle aged subjects	Nil	1 4 on month for 3 min telephone group 9 8 sessions/month for 29 min comparison group	No significant difference in mean number of exercise session month between groups Both group increased frequency over all	
No	100	Average age 39 9	Nil	2 month	No difference between group	

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1B *Summary of interventions: facility based*

Authors, year of publication, stated objectives	*Length of intervention*	*Location of exercise home or facility*	*Authors' description of exercise*	*Prescribed frequency, intensity, and duration of exercise*	*Controls*
M Auley[28] To determine the utility of an efficacy based intervention on exercise participation	20 weeks	Facility	Walking	3 × wk, 40 min	Initial instruction + exercise information classes
King[29] – To study the effect of two low cost methods of increasing the number of participant controlled jogging episodes	5 weeks	Facility	Jogging	4 × wk, individualised time and distance goals	Instructed to jog alone
MacKeen[30] To study the effect of an 18 month exercise intervention on adherence	18 months	Facility and Home	Jogging, swimming, game	3 × wk minimum, 35 75 minutes per session	Assessment only
Reid To assess the effectiveness of physician prescribed exercise programme with health education and self monitoring components	1 hour	Facility	Endurance activity	Advice about frequency, intensity, duration given but not described	Assessment and written exercise advice
Marcus [31] – To assess effectiveness of a relapse prevention programme and reinforcement programme in increasing exercise adherence and short term maintenance	18 weeks	Facility	Exercise to music class	35 50 minute 3 × wk	Attendance at exercise group, no behavioural technique

Follow up

Telephone calling was a common method for following up clients in home based trials after an initial instruction session. All of the home based trials where researchers maintained contact with clients by telephone reported positive outcomes. Studies 2 and 6 investigated the effect of telephone prompting. Study 2 randomised subjects to four levels of telephone prompting or to a control arm. All subjects received 15 minutes of instruction on walking. At six months there was a significant difference in numbers of subjects still walking between the three prompted arms and the control arm, and between prompt frequency (once per week versus once every three weeks). Study 6 randomly assigned subjects who were waiting list controls from a previous trial[35] to two interventions, one of which received telephone contact (10 times during six months). All subjects received instructions in behavioural methods to improve compliance. Subjects in the telephone prompting arm exercised more frequently and for longer than those in the control arm (12·4 sessions/month for 32 minutes versus 9·8 sessions/month for 28 minutes). This difference did not achieve significance. Only subjects in the telephone arm significantly increased their fitness.

Discussion

We have not attempted a formal meta-analysis of the trials in this review since this would be inappropriate in view of the incompatible data and varying quality of the trials described. This is in accordance with the criteria for attempting a meta-analysis described by Eysenck.[36] The important public health question is whether evidence exists to guide policy makers considering strategies to increase the activity levels of a sedentary population. Trials that were able to demonstrate significant increases in activity involved exercise that was home based, of moderate intensity, involved walking, and had regular follow up.

Walking from home was more successful than exercise which relied on attendance at structured exercise sessions. Only two facility based trials reported increases in exercise, compared with six of the home based trials. All those trials prescribing walking reported increases in activity. Moderate intensity activity was also associated with higher compliance rates. Walking on level ground at a brisk pace would be a moderate intensity activity for most people.

In Britain, walking is the most popular leisure time physical activity.[37] Approximately half the subjects in a recent national survey[11] walked continuously for at least a mile at least once in the past week. However, only 26% of men and 21% of women walked at a brisk or fast pace, and only 14% of men and 17% of women aged 55–74 walked at this pace. The 1993 Health Survey for England[12] confirmed these findings, reporting that 20% of women

2B *Summary of results, facility based*

Data analysed by "intention to treat"	*No in Study*	*Subjects*	*Post intervention follow up*	*Actual frequency, intensity, and duration of exercise intervention group*	*Main outcome P < 0·05*	*Outcome + or 0*
Yes	145	Previously sedentary, 45 64 year old	None	Not stated	Intervention subjects exercised more frequently and for longer than controls	+
Yes	58	18 – year old previously sedentary female psychology student	2 month	Mean frequency JAR and G = 2 4 week GR = 1 4/week	83 jogging alone + relapse subjects still exercising at follow up compared to 36 of control subjects	+
No	171	Males aged 40–59 with CHD risk factors	12 years	Mean hours jogging/week at year 13 0 3 hours	No difference between exercise and control condition at follow up on jogging hours per week	0
N	124	Male firefighters aged 24 56	6 months	Not stated	No significant difference between group at follow up	0
Yes	12	Previously sedentary, female university employees with a mean age of 35 years	2 months	Percentage of lapse attended during the 18 weeks RP 51 , R 49 , Controls – 44	No significant difference in attendance at 18 weeks or month follow up	0

high intensity group HIH, high intensity home, LIH, low intensity home JAR, jogging alone + relapse prevention, G, group jogging; GR, group g + relapse prevention, RP relapse prevention, R, reinforcement

and 30% of men were classified as moderate walkers (fast or brisk pace), and 38% of women and 32% of men classified as light intensity walkers (slow or average pace). Brisk walking is recommended for improving population activity levels by the American College of Sports Medicine and the Centres for Disease Control and Prevention(USA).[13] In England, the Health Education Authority's Active for Life campaign emphasises the importance of brisk walking for improving one's health.

A United States survey has shown that people in lower income groups, older people, women, blacks and Hispanic people participated in less exercise.[38] These differences were not seen in the numbers who were walking, which indicates that walking may be more universally accessible than other types of physical activity. In England, physical activity participation is lower in older people, women, those living in council properties, lower education groups,[11] and lower socioeconomic groups.[39]

Walking is also associated with a lower injury rate than other forms of physical activity.[40] Injuries are reported as a barrier to exercise particularly in older age groups.[11] Reviews of the determinants of physical activity report fewer barriers to walking than other types of physical activity.[41]

Some younger men and most other adults would improve their physical fitness if they took up regular brisk walking (fig 1).[42] Increases in cardiovascular fitness have been associated with reductions in cardiovascular and all-cause mortality.[43] A report on the health benefits of walking which reviewed the impact of walking on various cardiovascular disease risk factors concluded that "regular walking has the potential to lower blood pressure, improve the lipid profile, reduce body fat, enhance mental well-being and reduce the risk of coronary heart disease."[44]

This review has shown that when walking is recommended and attendance at a facility is not required, significant increases in activity can be achieved. When subjects are followed up regularly the increases can be maintained.

Our findings do not support the current trend in physical activity promotion in this country. There has been a rapid growth in general practitioner (GP) prescription for exercise schemes. Estimates suggest that hundreds of such schemes exist in all parts of the country. A 1994 report[45] found that a large proportion of such schemes are leisure centre managed, and involve GPs referring patients at reduced or no cost for an average period of 10 weeks. The report estimated that less than 1% of a GP's patient list was referred into the schemes and also highlighted the fact that "no examples of good evaluation" were found, preventing any conclusions about effectiveness. Although we have been informed of ongoing trials of such schemes, we were unable to find any results published in the scientific literature. The emphasis placed on attending a leisure facility and the neglect of walking as a form of exercise is inconsistent with the findings of this review.

Most of the studies used volunteers responding to advertisements to take part in a physical activity programme. One study (study 3) that used random digit dialling as a method of recruitment only randomised 27% of those actually contacted, suggesting a high degree of self selection.[46] These recruitment methods tell us little about how to increase the physical activity levels of the vast majority of people who are unlikely to respond to advertisements.

The findings of this review should be viewed with caution as they are based on only 12 trials all of which were carried out in the USA.

FUTURE RESEARCH

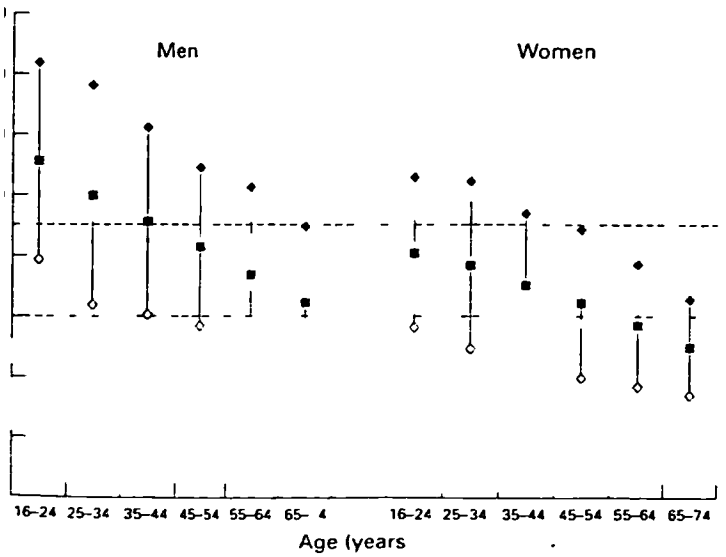
There is an urgent need for experimental research. In particular:

- there should be trials undertaken in the United Kingdom;
- trials should include groups other than the middle aged, middle class, and white;
- there is a need for trials specifically dealing with physical activity in the over 75s;
- there is a need for evaluation of GP prescription schemes by randomised controlled trials;
- there is a need to evaluate the effect of GPs advising their patients to exercise.

CONCLUSION

Levels of physical activity can be increased and the increase can be maintained for at least two years. Interventions that encourage walking and do not require attendance at a facility are most likely to lead to sustainable increases in overall physical activity. Regular follow up, which need not be time consuming and expensive, improves the proportion of people able to maintain initial increases

Brisk walking has the greatest potential for increasing the overall activity levels of a sedentary population and meeting current public health recommendations It is also the kind of exercise most likely to be adopted by a range of ages, socioeconomic, and ethnic groups as well a both sexes.



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In order to increase the attractiveness of walking for recreational purposes or as a mode of transport, attention will need to be paid to environmental factors which influence personal safety and convenience.

Summary

We have reviewed randomised controlled trials of physical activity promotion to provide recent and reliable information on the effectiveness of physical activity promotion. Computerised databases and references of references were searched. Experts were contacted and asked for information about existing work. Studies assessed were randomised controlled trials of healthy, free living, adult subjects, where exercise behaviour was the dependent variable. Eleven trials were identified. No United Kingdom based studies were found. Interventions that encourage walking and do not require attendance at a facility are most likely to lead to sustainable increases in overall physical activity. Brisk walking has the greatest potential for increasing overall activity levels of a sedentary population and meeting current public health recommendations. The small number of trials limits the strength of any conclusions and highlights the need for more research.

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Cost-effectiveness of a primary care based physical activity intervention in 45–74 year old men and women: a randomised controlled trial

W Stevens, M Hillsdon, M Thorogood, D McArdle

Abstract

***Objective*—To assess the cost-effectiveness of a primary care based intervention aimed at increasing levels of physical activity in inactive people aged 45–74.**

***Methods*—A total of 714 inactive people aged 45–74, taken from two west London general practices, were randomised into two groups. Intervention subjects were invited to a consultation with an exercise development officer, and offered a personalised 10 week programme to increase their level of regular physical activity, combining leisure centre and home based activities. Control subjects were sent information on local leisure centres. All subjects were followed up at eight months.**

***Results*—There was a net 10.6% (95% confidence interval 4.5 to 16.9%) reduction in the proportion of people classified as sedentary in the intervention group compared with the control group, eight months after the intervention. The intervention group also reported an increase in the mean number of episodes of physical activity per week, as compared with the control group (an additional 1.52 episodes (95% confidence interval 1.14 to 1.95)). The cost of moving a person out of the sedentary group was shown to be less than £650. The cost of moving someone to the now commonly recommended level was estimated at almost £2500.**

***Conclusions*—Moderate physical activity can be successfully encouraged in previously sedentary men and women aged 45–74 through a primary care based intervention. The process of recruitment was the most important variable cost. A high uptake rate would maximise cost-effectiveness, and sensitivity analysis suggests that unit costs could be halved with a more effective recruitment strategy.**

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Keywords: physical activity promotion; primary care; middle aged

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A recent report on physical activity and health by the US Surgeon General[1] highlighted the main effects of physical activity on health and disease: lower total mortality rates and decreased risk of cardiovascular mortality, colon cancer, and non-insulin dependent diabetes. In addition, regular physical activity prevents or delays high blood pressure, reduces blood pressure in those with hypertension, and relieves the symptoms of depression and anxiety. A meta-analysis relating to physical activity in the prevention of coronary heart disease concluded that the relative risk of developing coronary heart disease in the least active compared with the most active was 1.9,[2] similar to that of other risk factors such as smoking and hypertension.

It has been estimated that seven out of 10 men and eight out of 10 women take insufficient exercise to derive health benefits.[3] Current recommendations[4] are that adults should undertake either vigorous exercise three days a week for at least 20 minutes on each occasion or moderate intensity exercise five days a week for at least 30 minutes on each occasion. The first of these recommendations was derived mainly from the effect on cardiorespiratory endurance, but recently the benefits of less vigorous activity has become recognised, particularly for those who take little or no exercise. The recommendation of moderate activity is not meant to replace that for vigorous activity, but rather to complement it.

We report a randomised controlled trial of the effectiveness and cost effectiveness of a "Prescription for Exercise" scheme, based in primary care. The aim of the scheme was to increase levels of physical activity in inactive people aged 45–74.

Primary care was chosen as the base for the scheme to ensure recruitment of a wide range of participants, as representative as possible of the British population. It has been estimated that almost 80% of people visit their doctor's surgery at least once a year.[5]

Methods

RECRUITMENT TO THE TRIAL

To identify currently inactive people, a self assessment questionnaire was sent to everyone on the surgery list aged 45–74. The three page questionnaire asked for basic demographic data (education, ethnicity, marital status, and economic activity) and a self assessment of the number of episodes of moderate and vigorous exercise, undertaken for at least 20 minutes, in the last four weeks. A list of activities was included to describe typically moderate and vigorous activity in terms of the activities of everyday life (see table 1 . The questionnaire was adapted from a self administered seven day recall questionnaire used in other community

Table 1 Classification of moderate and vigorous activity

Moderate	*Vigorous*
Brisk walking	Jogging/running
Heavy gardening	Competitive sports
Cycling for pleasure	Swimming lengths briskly
Heavy DIY	Climbing stairs
Swimming leisurely	Fast cycling

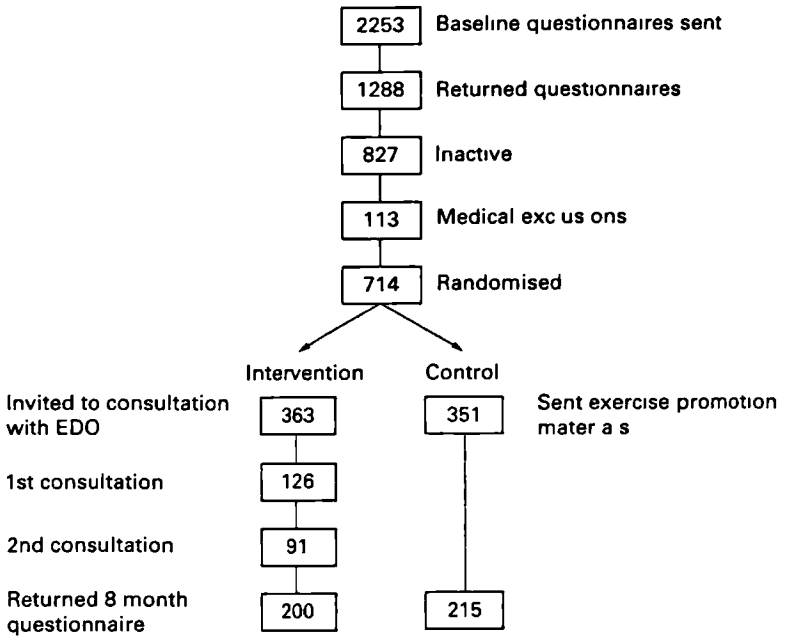

Figure 1 Study design. EDO, exercise development officer.

interventions.[6] People who returned the completed physical activity questionnaires were classified into four levels of activity:

(*a*) sedentary—fewer than four 20 minute episodes of moderate or vigorous intensity activity in the previous four weeks;

(*b*) low intermediate—between four and eleven 20 minute episodes of moderate or vigorous intensity activity in the previous four weeks;

(*c*) high intermediate—12 or more 20 minute episodes of moderate or vigorous intensity activity in the previous four weeks, but less than either of the current recommendations;

(*d*) active—a minimum of either 20 30 minute episodes of moderate intensity exercise or 12 20 minute episodes of vigorous intensity exercise.

Subjects in the first three groups were regarded as inactive and eligible for randomisation into the trial, unless there was a medical reason for excluding them—for example, being registered disabled or having a diagnosis of heart disease. Eligible subjects were randomised using a random number generator to either the intervention or the control group.

NATURE OF THE INTERVENTION

The intervention subjects were sent a letter from their general practitioner inviting them to attend a consultation with an exercise development officer at a local leisure centre, which was centrally located within the ward. The consultation consisted of:

(*a*) a full explanation of the scheme;

(*b*) a medical/lifestyle questionnaire/consent form;

(*c*) physical measurements (height/weight/body mass index);

(*d*) assessment of present activity level;

(*e*) options available to be more physically active;

(*f*) introduction to the physical activity diary.

An important aspect of the intervention was the lack of any preset goals or minimum achievements. Participants were made aware of the existing recommendations on physical activity and health, but they were neither expected nor pressured into achieving these standards. The options to become more physically active were designed to increase what the participants already did, rather than to try to force major changes to lifestyle.

The exercise programme lasted for 10 weeks, after which subjects were invited to return for a second consultation to discuss their progress.

Control subjects were sent information in the post on local leisure centres and health clubs along with information on physical activity and health. Figure 1 shows a summary of the trial.

OUTCOME EVALUATION

Eight months after randomisation, all subjects received a follow up questionnaire on self assessment of physical activity levels. The primary outcome of the trial was the change in reported levels of physical activity in the eight months between the completion of the baseline and follow up questionnaires. Subjects who did not complete the second questionnaire were assumed not to have changed their activity level.

STATISTICAL ANALYSIS

Statistical analysis was carried out using SPSS for Windows version 6.1. Differences between the intervention and control groups were tested using the comparison of means test and the *t* test of significance. Unless otherwise stated, results are described on an "intention to treat" basis, with those subjects for whom there was no outcome measure being assigned to the activity level they reported at the start of the study.

ETHICS

Ethical approval was given by the Ealing, Hammersmith and Hounslow Health Authority Ethics Committee.

Results

RECRUITMENT

The baseline questionnaire was sent to 2253 people, and 1288 returned completed questionnaires, a response rate of 57%. A comparison of the original general practice lists with the population returning the questionnaire showed that 63 % of women returned a questionnaire compared with 46 % of men. The response rate for subjects aged 65–74 years was 64%, while that for those aged 55–64 years was 54%, and the youngest age group (45–54 years) had a response rate of 37%. Of those who returned the questionnaire, 827 64) were classified as not active—that is, in the lower three activity categories—but 113 of them were excluded from the study on medical grounds. A total of 714 subjects were randomised into the two trial groups.

Table 2 *Demographic and health related characteristics of the sample*

	Intervention group (n=363)	*Control group (n=351)*
Percentage men	40	44
Mean age (years	59 1	59.2
Age band (%		
45 54	37	36
55–64	26	28
65–74	37	36
Body mass index (%		
<20	4	5
20–25	50	53
>25	46	42
Current smokers % of total	18	17
Demographics		
Economically active ( )	55	52
Ethnicity (%)		
White	87	83
Black	5	4
Asian	4	8
Other	4	5
Education (%)		
Degree/teaching	28	30
A level	12	12
O level/GCSE	11	15
Other	9	13
None	36	32
Physical activity level group (%)		
Sedentary	55	51
Low intermediate	42	45
High intermediate	3	4
Active	0	0

Table 3 *Mean number of occasions of physical activity in the four weeks before follow up*

	Intervention	*Control*	*Difference*	*95% Confidence interval*
Moderate physical activity	5.09	3.64	1.45	1.03 to 1.74
Vigorous physical activity	0 86	0.78	0.08	0.01 to 0 30
All episodes	5 95	4.43	1.52	1.14 to 1.95

RANDOMISATION

There were 363 subjects randomised to receive an invitation for a consultation with an exercise development officer (the intervention group) and 351 subjects randomised to receive an information pack on leisure centre facilities in the post (the control group). Table 2 gives details on baseline characteristics of the intervention and control groups, and shows that the groups were broadly similar, with no significant differences.

UPTAKE OF THE INTERVENTION EXERCISE PROGRAMME

Of the 363 subjects randomised to the intervention group, only 126 (35%) attended the first consultation with the exercise development officer. Ninety one subjects (25%) returned for the second consultation at the end of the 10 week exercise programme.

PHYSICAL ACTIVITY LEVELS AT FOLLOW UP

Table 3 shows the mean number of occasions of physical activity in the previous four weeks reported by the intervention and control groups at eight months follow up. It must be noted that all measures of physical activity are self reported and as such must be open to the usual levels of scrutiny. Both moderate and total occasions of physical activity were significantly greater in the intervention group. Vigorous activity was also higher in the intervention group but did not reach significance.

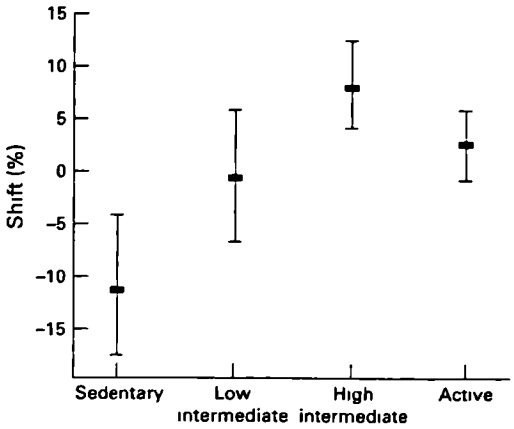

Figure 2 Change in the proportion of subjects in each physical activity level group, relative to the control, between baseline and eight month follow up, with 95% confidence intervals.

Table 4 shows leisure centre usage and total physical activity in subjects classified as sedentary and low intermediate at baseline (no high intermediate subjects completed all parts of the trial). Subjects who were more active at baseline were more likely to have used the leisure centre at some time during the four weeks before the first consultation while both groups increased their usage during the eight months. Table 4 also shows that at follow up both groups were exercising away from the leisure centre at least as often as they were exercising at it.

Figure 2 shows the percentage change in activity categories at eight months in both intervention and control subjects. There is a reduction in the number of subjects in the lowest two activity categories and an increase in the highest two categories in the intervention group, with similar but smaller changes in the control group. Figure 3 shows the eight month activity level of subjects by their baseline level of physical activity. Subjects not available at follow up (n = 163) were assumed not to have changed. Overall, 79 subjects moved into a higher level of physical activity with only 17 moving down. The biggest changes were from sedentary to low intermediate (14%) and low intermediate to high intermediate (14%). Few subjects moved into the active group.

COSTS

Recruitment costs were calculated using a top down approach. All resources were costed unless

Table 4 *Leisure centre usage and total activity by baseline level of physical activity in intervention subjects completing all stages of the study*

Baseline activity status	*Percentage of patients reporting using a leisure centre at 1st consultation*	*Mean number of visits to leisure centre in 4 weeks before baseline*	*Percentage of patients reporting using a leisure centre at 8 month follow up*	*Mean number of visits to leisure centre in 4 weeks before follow up*	*Mean occasions of physical activity in 4 weeks before follow up*
Sedentary n=55)	4	2.5	16	4.1	7.9
Low intermediate (n=36)	25	2.2	33	4.6	9.6

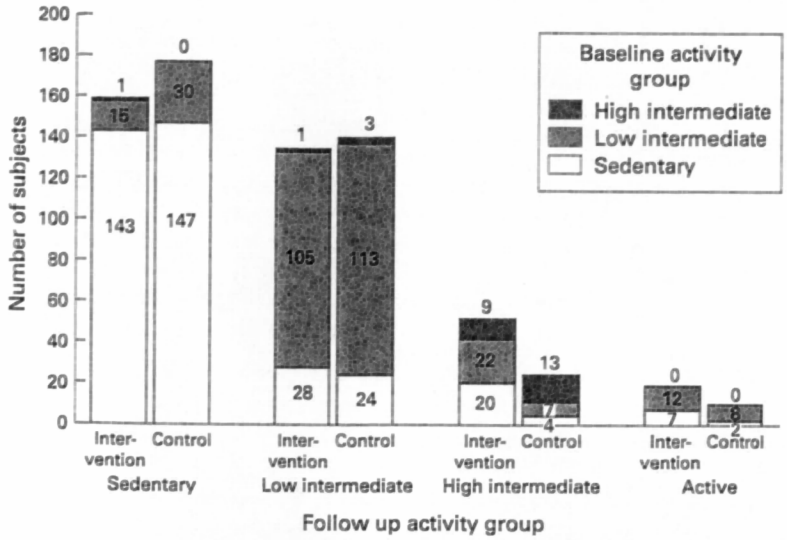

Figure 3 Number of subjects in each physical group at follow up by baseline group (intervention n = 363; control n = 351).

Table 5 Costs of recruitment by stage

	Stage 1 (identification as inactive)	*Stage 2 (invited for consultation)*	*Stage 3 (completed programme)*
Population	2253	363	363
Response	1288	126	91
Response rate (%)	57	35	25
Postage	£985	£227	£30
Stationery	£580	£145	£315
Labour*			
Admininistration	£952	£224	£840
EDO	—	£984	£18 040
Equipment	—	—	£4 819
Total costs	£2517	£1580	£24 044

*Labour costs include institution costs as well as wage costs; EDO, Exercise Development Officer.

they were deemed to be used for research purposes only. For costing of the baseline recruitment (stage 1), the costs of questionnaire design and production, mailing, and follow up of those people who did not reply first time were included. However, only one third of the cost of processing the data from the questionnaires was included, as about two thirds of the data were collected for research purposes, unrelated to carrying out the intervention.

Table 5 shows the participation and completion rates at each stage together with the costs of each stage. Stage 1 was the recruitment stage, involving the mailing, completion, and analysis of the baseline questionnaires, stage 2 was the process of invitation to an exercise consultation, and stage 3 was the intervention itself.

COST-EFFECTIVENESS

We used three measures of effectiveness in calculating cost-effectiveness. Firstly, we considered the cost of inducing one sedentary person to undertake more physical activity, the main intended outcome of the trial. This is measured by the net decrease in the proportion of sedentary people after the intervention net of the same decrease seen in the control group and gives a cost per person of £623. Secondly, we considered the cost of moving someone who is active, but below the minimum required level, to that minimum level. This is calculated as the proportionate increase net of the control group for the number attaining the top group classification. This was achieved at a cost of just under £2500 per person. Thirdly, we considered the cost of achieving any increase in an individual's level of physical activity. The cost of this was £327 for movement into a higher activity group or less than £200 for an absolute increase in physical activity. Table 6 gives a summary of the results.

Table 6 Cost-effectiveness of the intervention

	Reduction in no of sedentary people	*Increase in no of people who are active*	*Movement into higher level of physical activity*
Total cost	£24 043	£24 043	£24 043
Gross shift (%)	11.2	5.8	21
Net shift (%)	10.6	2.7	20
People equivalent*	38	10	73
Cost per person	£623	£2498	£327

*n=363.

SENSITIVITY ANALYSIS

Table 7 shows the breakdown of medium term fixed and variable costs for the intervention by stage. Most costs, such as the salary of the exercise development officer and the equipment, were fixed. The main factor that would affect the cost-effectiveness of the intervention is the take up rate. In this trial, there was a planned capacity of up to 363 attendees in the exercise programme, but a response of just 35%, leaving underused resources. Because this was a relatively small scale trial, the administrative work (posting, data entry, and appointment management) was carried out by the exercise development officer. On a larger scale, this work could be performed by a clerk at lower cost. The equipment costed for the project was underutilised, but also has a working life beyond the duration of the trial. Most of the equipment has a capital life of between five and 10 years and therefore annual equivalent cost was used to ensure a more realistic programme cost.

Sensitivity analysis shows no sizeable change to unit costs from the changes in definition of capital and administration costs, but table 8 gives details of the effect on unit costs when the stage one and two response rates are changed. The range of testing took the stage 1 response rate up to 74% and the stage 2 response rate up to 68%, rates that have actually been achieved in another continuing trial by one of us (M H). Variation in recruitment rates had a profound effect on unit cost. With a combination of a 74% response rate in stage 1 and a 68% response rate in stage 2, unit costs were less than half of that recorded during this intervention, assuming similar levels of adherence to the programme in all subjects. The response rate at stage 2 had the biggest effect on this. Recruitment strategy will be an important aspect of the cost-effectiveness of any exercise promotion intervention.

Table 7 Costs of intervention by stage

	Stage 1 (identification as inactive)	*Stage 2 (made available for consultation)*	*Stage 3 (completed programme)*
Total costs (£)	2517	1579	24 043
Fixed costs (£)	952	1208	23 698
Variable costs (£)	1565	371	345

Table 8 *Sensitivity analysis and cost consequences (£)*

	Cost per complete programme attender	*Cost per sedentary person reduced*	*Cost per person classified as active*	*Cost per person moved up a group*
Current programme	279	623	2498	327
Response rate at stage 1				
60	252	588	2295	310
65%	236	550	2145	290
70	222	517	2018	273
74	212	494	1928	260
Response rate at stage 2				
40	236	550	2145	29
50%	197	460	1793	242
60%	172	4 2	1566	212
68%	158	368	1437	194
With stage 1 response rate at 74%, response rate at stage 2				
40%	182	424	1652	223
50%	152	354	1381	187
60%	133	309	12 6	163
68%	122	284	1107	150

Discussion

This study is the largest United Kingdom based randomised controlled trial to date evaluating physical activity promotion in primary care. It provides encouragement for the continuing development of a primary care based physical activity strategy.

One difference between this study and other "Prescription for Exercise" trials reported in the literature is that in this trial general practitioners were not directly involved in either the recruitment of subjects or the intervention itself. An exercise specialist was used at both stages. Other trials have found it difficult to recruit using general practitioners, because the competing demands on the general practitioner's time lead to the activity intervention taking a low priority, with low levels of recruitment and a focus on patients at lower risk of health problems (mainly younger women who want to lose weight).[7 8] If physical activity promotion is going to make an impact on population health, then the intervention needs to be made available and attractive to those with the most health benefit to gain.[9] This study also showed a higher proportion of women attending the first stage of the intervention. Different methods for recruiting men to such interventions need to be identified.

One possible method of increasing the priority of physical activity promotion is to have a dedicated member of staff. The person used in this study was an exercise specialist with relevant qualifications. What remains unclear is whether or not this level of expertise would necessarily be required in a non-research intervention. Also, this study only used one exercise development officer and therefore it is unclear as to whether any particular characteristics of this person influenced the outcomes of the study, limiting the generalisability of the results. It is difficult to assess the impact of this "therapist effect", because of the lack of similar trials for comparison. Future interventions could be run by existing primary care staff such as a community physiotherapist or a practice nurse. This would involve additional training, and its associated costs, but this may be offset by lower overall wage costs.

Although the proportion of subjects who made use of the leisure centre increased during the course of the study, most physical activity was undertaken away from the centre. Environmental efforts focused on increasing opportunities for activities not requiring attendance at a leisure centre, such as walking, may have a greater impact on the prevalence of inactivity.

The cost-effectiveness analysis showed the importance of the success in recruitment. A high take up of the offered advice enables better management of the expensive resources, particularly the personnel, and even a small difference in take up rates at each stage could have sizeable effects on the cost of achieving outcomes.

We identified two areas where a change in the organisation of the trial might have improved response.

(1) The letter of invitation specifically mentioned exercise and could have been interpreted as being critical of the patient's current less than active lifestyle. A copy of the letter is shown in the appendix. People are usually reluctant to come to any consultation if they expect to be "told off". The method of invitation should be designed to be as non-judgemental as possible. We have experienced more success in recruiting in another continuing trial with a more neutral invitation letter.

(2) The letter of invitation to a consultation did not include a set consultation time. It asked for the recipient of the letter to take the initiative in arranging an appointment. Again, a higher response has been achieved when an appointment time is given and the recipient is asked to cancel or rearrange it if not convenient.

More research into optimal methods of recruiting participants for all primary care based health promotion initiatives is needed.

This study has shown that it is possible to reduce the proportion of sedentary people in this population, but it is more difficult to achieve the current recommended levels of activity. We have seen an increase in the level of physical activity for subjects in each of the baseline activity levels. Small gradual changes in activity behaviour seem to be more achievable than major ones, and an increase in moderate intensity physical activity has proved easier to achieve than an increase in vigorous intensity activity. The lack of objective measures to corroborate self reported physical activity in this study should be considered when interpreting these findings.

Some commentators have argued that any increase in the level of physical activity among older people, especially those who are sedentary, will be of benefit to their health.[4 1] The definition of positive outcomes in physical activity interventions should be broad enough to include small gains in those at greatest risk, rather than setting a threshold below which any activity is seen as being of no value. We should concentrate on changes in lifestyle that are achievable, because a small gain for a lot of people can represent a large gain for the health of the population.

CONCLUSIONS

This study has shown that it is possible to increase levels of physical activity at a moderate intensity in men and women aged 45–74 through a primary care based intervention. The results f the cost-effectiveness analysis show that the recruitment process was the most important aspect of the intervention. To maximise cost-effectiveness it is important to have a high take up rate. Sensitivity analysis suggests that unit costs can be halved with a better recruitment strategy.

We would like to thank Pat Mahoney for the original idea, the d ctors and patients at both the Avenue Crescent Practi e and Southfields Medical Centre as well as Ealing Leisure Services for their cooperati n and assi tan e with this pr ject This trial was supported by West London Health Promotion Agency through a grant awarded by N rth Thames NHS Executive Responsive Funding Programme RFG01) W S, M H, and M T are all supported by the Health Gain Project, funded jointly by North Thames NHS Executive and the Health Educati n Auth rity.

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Appendix: Invitation to meet with exercise specialist

Dear Sir madam,

Thank you for taking the time to return your Physical Activity Questionnaire. The information has been invaluable in helping to provide a picture of the health needs of our local population.

It has been well established that physical inactivity is a major factor contributing to coronary heart disease.

I have arranged a consultation with an exercise specialist for you. He will advise you on how to incorporate a greater degree of physical activity, helping you to maintain an active and enjoyable lifestyle. The consultation will look at what kind of physical activity you would get the most benefit from. It will take into account your personal circumstances and what facilities and activities are available to you.

To fix an appointment please fill in the enclosed card and post it in the reply paid envelope.

Yours sincerely
Dr X

Commentary

This paper shows the modest effectiveness of a prescription for exercise scheme based in primary care. In two urban practices, 2253 patients were sent questionnaires, based on a response rate of 57%, and 64% were found to be sedentary. After randomisation to consultation with an exercise development officer, eight months later 204/363 = 56% were active in the exercise prescription group compared with 174/351 = 49°₀ in the control group (odds ratio = 1.30; 95% confidence interval = 1.27 to 1.34). While this improvement is encouraging, the fact that only 12°₀ of the sedentary individuals at risk actually would have benefitted from such a programme limits its effectiveness as a useful strategy. This limited penetration of physical activity to the at risk population is especially important since disabled patients and those with coronary heart disease, who would both benefit from increased physical activity, were excluded from this study.

The principal advantage of addressing physical activity in the primary care setting is to build on the continuity of care over time that primary care practitioners provide and the ability of the primary care provider to motivate patients at teachable moments. The strategy presented in this report does not incorporate these aspects of primary care. The cost analysis is revealing and demonstrates the high cost of making people active and relatively low cost of increasing activity levels to higher levels in those with intermediate levels of physical activity. The lessons learned from this trial and others[1 2] in primary care will in time lead to effective physical activity counselling. Ultimately, I am confident that a cost-effective method that utilises both physician and health care team members and appropriate social and economic reinforcements will be found.

C B EATON
Pawtucket, Rhode Island

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Promoting physical activity: Issues in primary health care

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In the past few years, alliances between primary care and leisure services have become a popular strategy for exercise promotion in the England. 'GP Referral Schemes' typically involve referral to a local leisure centre by a General Practitioner (GP), whereupon patients are inducted into a 10–12 week exercise programme at a reduced fee. Referred patients are usually white, middle aged and apparently healthy women, with the main reason for referral being overweight. The schemes are characterised by their lack of formal evaluation, making conclusions about effectiveness impossible. In the US, physicians advice to exercise has been the focus of interventions to date. Two controlled trials, one randomised, have provided some evidence that exercise behaviour can be changed, at least in the short term. The ability to recruit sufficient numbers of patients, who have potentially the most to gain from increased physical activity, is the biggest barrier to primary care based interventions. One contributing factor to this problem, may be doctors and nurses' knowledge about the benefits of physical activity.

Keywords: GP referral; evaluation; recruitment

Introduction

This paper provides an overview of the promotion of physical activity in primary care in England. The importance of primary care in promoting physical activity, was highlighted in a report of the US Preventive Services Task Force, which recommended clinicians 'counsel' patients to incorporate physical activity into their daily routine, to prevent coronary heart disease (CHD).[1] The recommendation was based on the evidence for the reduced CHD morbidity associated with increased physical activity and physical fitness. However, the report also acknowledged the lack of evidence on the effectiveness of counseling, for promoting changes in physical activity.

At the same time, a survey in England reported a growing trend in primary care-based physical activity promotion schemes.[2] The survey identified 157 existing schemes and 35 planned schemes. Current estimates are, that most local authorities in the country either have a scheme or are intending to establish one in the near future. As with the Preventive Services Task Force report,[1] no evidence of the efficacy of such schemes was identified. This was mainly due to lack of evaluation built into the schemes identified. A systematic review of randomised controlled trials of exercise promotion also found no evidence for the effectiveness of primary care-based exercise interventions.[3] Although no primary care-based studies were identified that met the inclusion criteria, some successful criteria for promoting physical activity were found. Successful outcomes were associated with informal home-based physical activity of moderate intensity (usually walking) with brief professional contact often by telephone. These programme components are not those usually found in primary care programmes in England.

The review by Fox *et al*[2] found two main types of scheme; leisure centre-managed schemes and practice-managed schemes. The leisure centre-managed schemes were by far the most common and had a consistent design. Most involved a GP identifying suitable patients and then completing a 'prescription' for an initial visit to the local leisure centre. The prescription would entitle the bearer to a subsidised programme of exercise classes over the subsequent 10–12 weeks. At the end of this period most patients were encouraged to enroll as normal customers.

This model is problematic for a number of reasons. Firstly, the requirement to attend a facility and join structured exercise classes is inconsistent with the findings of Hillsdon and Thorogood.[3] Frequently reported barriers to physical activity such as lack of time and not seeing one self as the 'sporty type'[4] are more likely to be evident in facility-dependent schemes, compared to home-based schemes. The second problem lies in the dependence on GPs for referrals. The assumption that GPs are able to identify those patients with the most to gain from increased physical activity is flawed. A study aimed at identifying GPs and practice nurses' knowledge about physical activity found large gaps in specific knowledge of the health benefits of physical activity.[5] Both GPs and practice nurses ranked physical inactivity behind

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moking, increased blood pressure and a fatty diet, as risk factor for CHD. Knowledge of other health onditions apart from CHD that might be prevented y physical activity was weak, with inconsistency etween GPs and nurses. While GPs had obesity at he top of their list, nurses put weight reduction much ower. Hypertension and depression, two conditions nown to benefit from physical activity, did not ppear on the GP list. This apparent lack of knowldge is reflected in the type of patients referred to eisure centre schemes

An evaluation of a scheme in Stockport showed that he main reason for referral was being overweight, epresenting 32% of all referrals.[6] Only 5% of patients vere referred for 'lack of exercise'. No patients were eferred for hypertension or non-insulin dependent iabetes (patients with unstable hyperternsion and nsulin dependent diabetes were screened out). Similar atterns of prescription have been found in another cheme in the Wirral.[7] Identifying patients most likely o benefit from physical activity schemes is not only imited by lack of knowledge. More knowledgeable rimary care staff have been frustrated by their nability to refer the patients they would like to, due o screening criteria imposed on them by their health uthority.[8]

Another concern with recruitment is the low umber of men taking up such schemes. In the Stockort scheme only 25% of patients referred were men. erhaps the biggest concern about relying on GPs for atients is the low overall rate of referral. The review y Fox *et al*[2] could not find any schemes that drew on nore than 1% of the patient base of participating GPs. pilot study in Wales only enrolled 38 patients over a our month period from seven general practices. The otential number of referrals is high, as approximately 0% of the population are regarded as sedentary (that , exercise less than once per week).[4]

The health benefits of exercise cannot be stored. egular physical activity has to be sustained over the ng term in order to be protective against CHD. herefore, adherence to any programme of physical ctivity is of particular importance. In the Stockport tudy, 40% of subjects did not attend for their first ppointment at the leisure centre and only 15% of nose referred were reported to be exercising six nonths later. How much exercise was being underaken at this time was not reported. The 'prescription or exercise' scheme in the Wirral reported 20% of eople attending the pre- and post-12 week consultaon during the first two years. Although the authors eport an increase to 56% after the first two years, gain it is not known what amount of exercise was eing undertaken. A recently published randomised ontrolled trial of a scheme in East Sussex,[9] found that nly 38% of intervention subjects completed all ssessments during the nine months of the study. his study is the only one to date to have a control roup and to have physical activity as a main outcome easure. At follow up, there were no significant differences between intervention and control subjects in self-reported physical activity and body mass index (BMI).

An alternative to relying on GPs to refer patients for exercise is to contact patients directly. Two primary care-based studies (one ongoing) recruited patients directly from patient lists and not through referral from GPs. Both studies sent baseline questionnaires to all patients registered within the target age range of 45 74 y. Based on self-reported physical activity from returned questionnaires, patients were categorised as 'inactive' and suitable for recruitment. Subjects randomly assigned to intervention groups were invited either to a routine health check (Move-It study) or to an initial consultation with an exercise development officer based at a local leisure centre (Prescription for Exercise (PFE) study). Recruitment rates are shown in Table 1.

This approach to recruitment, results in larger numbers of subjects receiving an intervention than studies depending on GPs for patients. Both of these studies recruited the number of subjects shown in Table 1 over a 12-month period. The PFE study had a 50% lower attendance at the first appointment than the Move It study. This may, in part, be explained by the method of invitation. In the Move It study, participants were sent an appointment time and date at the medical centre, placing the responsibility for canceling the appointment on the participant. Also, participants were invited to a health check which did not imply engagement in an exercise intervention. PFE participants were sent a letter from their GP pointing out the importance of regular physical activity and asking them to make an appointment with an exercise development officer. Participants were required to return a slip indicating preferred times for appointments. In this case they were quite clear that by attending they would at least be receiving advice about taking up regular exercise. Arguably, attenders in the PFE study would be more self-motivated to exercise than those in the Move It study. PFE intervention subjects who did meet with the exercise development officer discussed options for increasing physical activity, which included the offer of a 10 week low cost leisure centre programme. The

Table 1 Comparison of patient responses in the Move It study and the Prescription for Exercise (PFE) study

	Move It[a]	*PFE*
Returned baseline questionnaire	74%	57%
Proportion inactive (of returned questionnaires)	44%	36%
Exclusions (mainly medical)	16%	14%
Randomised subjects	84% (*n* 787)	86% (*n* – 706)
Intervention group (*n*	518	363
Attendance at first appointment[b]	68%	34%
Proportion of male attenders	49%	40%

[a]The Move It study is ongoing and data is only preliminary.
[b]Routine health check in Move It study. Consultation with exercise development officer in PFE study.

Box 1 Practice implications

- Primary care staff require more education about the role of physical activity in the prevention and treatment of disease.
- Leisure fitness centres should not depend on primary care staff as the main source of referral.
- Patients should be given a choice about the type of exercise available, including home based activity.
- Better methods of recruitment need to be identified.
- Secondary prevention programmes targeting high risk groups may be most cost effective for primary care.
- There is an urgent need for evaluation of primary care physical activity inverventions.

proportion of subjects classified as sedementary in the intervention group had reduced by 10.7% at the 8 month follow up, which was significantly different from the control group.[10] These results provide some encouragement for future interventions.

Observations from GP referral schemes and from the Move It and PFE studies, highlight the importance of targeting specific groups. If overweight or obese people are the target group, then they might be identified from existing GP databases and contacted directly. If this approach were to be adopted, the question remains as to who would deliver the intervention. In the PFE study the exercise development officer was an employee of the local health promotion agency and had a background in exercise science. The cost effectiveness of this scheme is currently being evaluated.

Although a number of randomised controlled trials are underway in the UK, to date there are no reliable results. Therefore it is difficult to make any conclusions about future interventions (see Box 1). Outstanding questions relate to difficulties of recruitment, both in terms of identifying target groups and attracting large enough numbers to interventions to make them cost effective. One possible solution warranting further investigation is to limit primary care interventions to high risk populations known to benefit from increased physical activity. This would include people with obesity, hypertension, non insulin dependent diabetes, depression and those recovering from myocardial infarction. A review of multiple risk factor interventions provides some evidence for a secondary prevention approach.[11]

Another area warranting further exploration is brief interventions. Studies of brief instruction from a GP to quit smoking and reduce alcohol intake has produced some encouraging results.[12,13] Two studies in the US have attempted to assess similar methods in physical activity. Project PACE (Physician-based Assessment and Counseling for Exercise) was a non-randomised controlled trial of physician counseling to promote the adoption of physical activity in sedentary patients. Subjects received 3 5min of tailored counseling based on their readiness to take up physical activity. Self reported physical activity was assessed 4 6 weeks after the intervention. Subjects in the intervention group increased their amount of walking significantly more than controls.[14] The physicians in this study were volunteers who were interested in physical activity and the results were only reported on those available at follow up, limiting the generalisability of the results. In the second study, physicians were randomly assigned to give brief advice to patients who were attending for routine consultations. At one month follow up, intervention subjects reported a significant increase in duration, but not frequency of exercise.[15] A short follow up period and reliance on self-reported physical activity also limits the generalisability of this study.

GPs will require further training in the benefits of physical activity prior to undertaking this kind of work. Some encouragement can be drawn from existing schemes that have been able to successfully recruit overweight people. What is required now, is more research to evaluate whether the interventions currently on offer can achieve sufficient exercise adherence, to improve weight control in the longer term.

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